

BLOOD SAMPLE RELIABILITY USING INTRAVENOUS LINES

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ABSTRACT

Patients receiving care, whether arriving in the Emergency Department, or admitted to the ward, often have intravenous lines for the purpose of treatment. Yet, even with a preexisting vascular access device being available, we continue to use phlebotomy as the gold standard for blood specimen collection. If nurses and medical technicians could use a preexisting intravenous lines for blood collection there would be a reduction in patient care costs, increase in patient comfort, and increase in expeditious care. The purpose of this study was to investigate the interchangeability of specimens collected using infusing intravenous lines versus traditional phlebotomy collection methods.

This study was designed to be a quasi-experimental operational replication of a study completed in 1999 by Himberger and Himberger (2001). Their study evaluated the interchangeability of 12 commonly performed laboratory tests and concluded the two collection methods yielded interchangeable results.

Following Institutional Review Board approval a sample of 30 patients was used for the study. Enrollment occurred through the Malcolm Grow Medical Center Emergency Department. Subjects were identified and informed consent was obtained, the specimens were collected and tested. The results were evaluated using a paired *t* test and agreement analysis method and it was determined that specimens collected through infusing intravenous lines, simultaneously with phlebotomy, are interchangeable using this protocol.

Key Words: **blood sampling intravenous interchangeability reliability chemistry chem 7 complete blood count CBC phlebotomy**

BLOOD SAMPLE RELIABILITY USING INFUSING INTRAVENOUS LINES

by

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FOREWARD

The contents of this report reflect years of ongoing research that began in 1997 and will continue after this report. It has been a personal goal to attempt to validate better and improved methods of delivering patient care to those we serve. The specific intent of this research was to provide an avenue of treatment options to fellow soldiers deployed around the world with limited resources. Having been in several contingency situations myself, I realize how limited resources can be, including manpower, supplies and time. Hopefully the results of my work will be able to help further our purpose of existence, improved care and lifesaving in the military setting.

DEDICATION

I would like to dedicate this research to the people in my life that have made it possible.

To my wife Laura, without who's understanding and patients, I would not have been able to allocate the time to complete this project. Her strength in caring for our children, when I should have been, was amazing.

My children, Morgan, Jacob, and Rebecca, who have given up all the hours of play time without complaint and tolerated my labile moods as I spent hour's pouring over the data.

To there amazing talent to find other things to do while "daddy's working on school".

To my mother, thank you for instilling in me the determination to see this through.

Most of all to my father John B. Himberger. A man that believed fully and without reservation in the military and military health care. His guidance, motivation, and patriotism were the things that lead me to my military career. I can only hope that I can serve for 48 years as he did and only regret that with his passing in March of this past year he will not be able to share with me my pride with the completion of this project.

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CHAPTER I: INTRODUCTION

Background

Patients classified as “critically ill” in the community are given priority at hospitals. This priority is based both on the definitions determined by the local community and standards set by medical agencies (American College of Surgeons, 1993). Additionally, there are Federal and military guidelines that assist with the development of these standards. These “critically ill” patients, once in the hospital, receive expeditious care over other patients already receiving care, or who subsequently present to the emergency department or casualty receiving area. These critical patients are defined as those most in need of medical resources, and they are identified through a process known as triage, which is particularly useful in mass casualty situations.

Although standards slightly vary from the civilian institution to the military, the fastest medical evaluation possible is deemed vital to assuring the best possible care for critical patients. Several diagnostic tests are necessary to fully evaluate these patients because care decisions will often be based on the results.

The values of baseline laboratory studies in the diagnosis and treatment of injured and ill patients are universally accepted as the standard of care. The hematocrit has been identified as particularly useful in hypovolemic and trauma patients because they frequently require transfusion of blood products (Oman, 1995). Faster methods of analyzing the hematocrit have been investigated in an attempt to decrease the mortality and morbidity of trauma patients (Bartfield, Robinson, & Lekas, 1992). It is also important to investigate faster ways in obtaining blood specimens for analysis of basic hematological and chemistry values. These values include the white blood cell (WBC)

count, red blood cell (RBC) count, hemoglobin (Hgb), hematocrit (Hct), platelet (PLT) count, sodium (Na), potassium (K), chloride (Cl), glucose (Gluc), carbon dioxide (CO₂), creatinine (Cr), and blood urea nitrates (BUN). The goal of providing care to the most seriously injured or ill patient is to assess and obtain as much information in the shortest period of time, allowing for faster lifesaving interventions. Currently there is a common delay in obtaining blood specimens due to the requirement of phlebotomy as the gold standard of sampling. Faster methods of obtaining these samples and faster analysis of these values will expedite patient care and improves outcome. Very limited studies have been done in the area of blood sampling through peripheral intravenous lines (PIV). The most recent study by Himberger and Himberger (2001) showed promising results ($p < .05$) in the reliability of samples obtained through infusing intravenous lines, suggesting interchangeability with venipuncture specimen collection. Further research is needed in this area to validate the method of blood specimen collection through intravenous lines, the benefits, and the limitations of this method of collection.

Purpose

The purpose of this study was to replicate and extend prior research on the reliability of baseline laboratory blood values obtained from PIV lines (Himberger & Himberger, 2001). Previous research has demonstrated that it is possible to collect laboratory blood values from IV sites or near intravenous sites with some limitations. The data collected in a previous study indicates a low margin of error ($p < .05$) using an agreement analysis technique as described by Bland and Altman (1995) for specific laboratory values obtained from an infusing IV when compared to venipuncture (Himberger & Himberger, 2001). The study by Himberger and Himberger further

concluded that even when analyte values were outside the 95% level of agreement, they were not of clinical significance. However, with the exception of arterial and central lines, current clinical practice continues to use venipuncture when obtaining blood specimens. The study is to address the accuracy and reliability of 12 blood test values drawn from peripheral intravenous lines. These 12 baseline blood specimens were initially evaluated in the Himberger and Himberger (2001) study and are the most frequently used tests in the medical treatment of patients. These tests include (a) WBC; (b) RBC; (c) Hgb; (d) Hct; (e) PLT; (f) Na; (g) K; (h) Gluc; (i) Cl; (j) CO₂; (k) Cr; and (l) BUN.

Research Hypotheses

Are these 12 laboratory values reliable when drawn from an infusing peripheral intravenous line as compared to a specimen drawn at the same time using venipuncture? Can the study by Himberger and Himberger (2001) be replicated? Drawing baseline laboratory studies using the same methodology and operational replication of the study by Himberger and Himberger was used to test the hypotheses of this study. An agreement analysis technique as described by Bland and Altman (1995) was used to analyze the data and test the following hypotheses:

1. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 15\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in WBC counts in blood obtained from PIV compared to venipuncture.

2. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 6\%$ difference using Proficiency Test Provider standards

as recorded by the College of American Pathologists (1999), in RBC counts in blood obtained from PIV compared to venipuncture.

3. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 7\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Hgb values in blood obtained from PIV compared to venipuncture.

4. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 6\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Hct values in blood obtained from PIV compared to venipuncture.

5. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 25\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in PLT counts in blood obtained from PIV compared to venipuncture.

6. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than ± 4 millimoles/liter difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Na values in blood obtained from PIV compared to venipuncture.

7. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than ± 0.5 millimoles/liter difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in K values in blood obtained from PIV compared to venipuncture.

8. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 5\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Cl values in blood obtained from PIV compared to venipuncture.

9. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 10\%$ or 6 milligrams/deciliter difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Gluc values in blood obtained from PIV compared to venipuncture.

10. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than 8% or ± 5 millimeter mercury difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in CO₂ values in blood obtained from PIV compared to venipuncture.

11. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 15\%$ or 0.3 milligrams/deciliter, whichever is greater, difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Cr values in blood obtained from PIV compared to venipuncture.

12. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 9\%$ or 2 milligrams/deciliter, whichever is greater, difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in BUN values in blood obtained from PIV compared to venipuncture.

Relevance and Significance to Nursing

When receiving an unstable patient either in a civilian or military facility or on the battlefield, there is often at least one intravenous line (IV) infusing. During the prioritization of care and lifesaving interventions there is frequently a delay by the staff in obtaining blood specimens. Difficulties obtaining venous access of patients is a common cause of delay in specimen collection, costing the medical staff time and resources, which would be better allocated elsewhere to improve patient care. Nurses, functioning as members of receiving health care teams, play a pivotal role in the collection and evaluation of specimens as well as the treatment rendered to patients. They are often the first health care providers to contact the patient in the treatment facility. If nurses could use previously established IV lines for obtaining baseline blood studies, time and resources would be saved, and patient care would be expedited.

The significance of this study is: (a) utilizing peripheral intravenous (PIV) sites for blood specimen collection would result in faster baseline laboratory results; (b) with faster laboratory results, it is possible to provide faster, more accurate medical/nursing care to the patient and interventions such as medication, blood, and IV therapy could be accomplished in a timelier manner; (c) this methodology will provide the opportunity for singular improved vascular access in critically injured patients suffering from vascular collapse due to trauma such as those experienced during war time, by utilizing previously established IVs; (d) there would be a decreased risk of infection and other complications due to a decreased number of invasive venipunctures, particularly important in field and contingency situations (Suddarth & Brunner, 1991); (e) there would be increased patient comfort due to fewer painful venipunctures; and (f) there would be decreased cost related

to care of the patient, both in supplies as well as procedural time from medical staff. This allows for maximum utilization of supplies during times of war or contingencies. It would also improve the ability to receive mass casualties from the field by reducing the necessary time for diagnostic laboratory tests to be obtained, and reducing the time to treatment of those patients based on the results.

Conceptual Framework

The health promotion model developed by Pender was used during this study as a basis of theory (Polit & Hungler, 1993). The belief that disease is not a determinant of a person's health and wellbeing, but rather the development of resources that maintain or enhance health is a pivotal foundation of this study. Although the predominant emphasis of this model tends to be health education, it is also important to focus resources on the enhancement of health. If a preexisting intravenous device could be utilized for blood sample collection, patients would benefit from increased comfort and expeditious care. These methods of blood collection would become a vital resource in the maintenance and enhancement of health for patients. This method would allow the patient to have a positive experience with their health care and would possibly enhance their own attitude toward health. It has been noted that nurses have the potential to lead the health promotion movement in the future (Benson & Latter, 1998). Nurses are often the only health care providers to contact in-patients during blood specimen collection. By offering this option of treatment it is possible for nurses to lead the way in developing health and well being for patients. This study is one opportunity for nurses to begin leading the way, with the investigation of alternative care modalities.

Definitions

The following were the basic definitions (Kee, 1998) and the normal accepted results of the laboratory values used by this study for investigation (Wallash, 1996). It is important to note that different laboratories can report similar values with small variations. The values that follow should only be used as reference. This study used the patients as their own control, comparing two values drawn using different methods.

Noted in the last line of each item described is the definition Malcolm Grow Medical Center, the site of the data collection. Malcolm Grow Medical Center standards were referenced throughout this study as a representation of Air Force policy and procedures.

White blood cells (WBC): Counts are generally used to evaluate infection states in a patient. Normal values of the WBC for males and females over the age of 18 is 4.0-10.5 microliters/millimeter cubed. Malcolm Grow Medical Center reports this value to the nearest 1/10th number/microliter.

Red blood cells (RBC): Counts are considered the nutrient cells of the body. They are responsible for the transportation of oxygen and other nutrients as well as waste products. RBC values may vary with age and gender. For adults age eighteen and older the values are 4.2-6.5 million/microliters x 10^{12} /liter for males and 4.2-5.4 million/microliters x 10^{12} /liter females. Malcolm Grow Medical Center reports this value to the nearest 1/10 number/microliter.

Hemoglobin (Hgb): Is a protein substance that is found on red blood cells and represents the oxygen carrying capacity of blood. Hemoglobin values may vary with age and gender. For adults age eighteen and older the values for males are 13.5-18.0

grams/deciliter and for females, 12.5-16.0 grams/deciliter. Malcolm Grow Medical Center reports this value to the nearest 1/10 of a gram/deciliter.

Hematocrit (Hct): Is reported as the percent of packed red blood cells in milliliters per deciliter of blood. Hematocrit values may vary with age and gender. For adults age eighteen and older the values are 42-52% and 37-47% for males and females, respectively. Malcolm Grow Medical Center reports this value to the nearest 1/10 of a percentage.

Platelets (PLT): Are basic elements in the blood that promote coagulation. The normal value of the platelet count is 150,000-400,000/cubic millimeter using the Coulter counter. Malcolm Grow Medical Center reports this value to the nearest 1000 cells/microliter.

Sodium (Na): Is the major cation in the extracellular fluid and has a water-retaining effect. The normal value of sodium is 135-145 milliequivalents/liter. Malcolm Grow Medical Center reports this value to the nearest full millimole/liter.

Potassium (K): Is the electrolyte found most abundantly in intracellular fluids. The normal value for potassium is 3.6-4.8 milliequivalents/liter until age 60 then 3.9-5.3 milliequivalents/liter. Malcolm Grow Medical Center reports this value to the nearest 1/10 of a millimole/liter.

Glucose (Gluc): Is formed from dietary carbohydrates and stored as glycogen in the body. The normal fasting glucose value is 60-110 milligrams/deciliter. Malcolm Grow Medical Center reports this value to the nearest milligram/deciliter.

Chloride (Cl): Is an anion found mostly in extracellular fluids. The normal value of chloride is 96-109 milliequivalents/liter. Malcolm Grow Medical Center reports this value to the nearest full millimole/liter.

Creatinine (Cr): Is a by-product of muscle catabolism and is derived from the breakdown of muscle creatine phosphate. The normal value for ages sixteen and older is 0.8-1.2 milligrams/deciliter. Malcolm Grow Medical Center reports this value to the nearest 1/10 millimole/deciliter.

Blood Urea Nitrates (BUN): Is formed as an end product of protein metabolism. The normal value for patients ten and older is 8-21 milligrams/deciliter. Malcolm Grow Medical Center reports this value to the nearest 1/10 milligram/deciliter.

Carbon dioxide (CO₂): Acts as a bicarbonate (HCO₃) determinant and is performed to determine metabolic acid-base abnormalities. The normal value for carbon dioxide is 17-31 milliequivalents/liter. Malcolm Grow Medical Center reports this value to the nearest full milliequivalent/liter.

Assumptions

The disease process of any individual may change the normal findings of any laboratory study in numerous ways. However, during the replication of this study simultaneously analyzed the effects of PIV blood specimen sampling to those results of traditionally obtained specimens from venipuncture, and would expected any variation from normal to be consistent in both specimens.

An additional variable within the study that could have had a strong impact on the results was the equipment used to provide care and analyze labs. Testing and reliability of the complete blood count analyzer, Coulter GenS, was maintained and monitored by the local facility laboratory. All maintenance was performed by the facility biomedical equipment department and is dictated by recommendations of Coulter Electronics (Coulter Corporation, 1994) and local laboratory policy. No machine analyzer

malfunctions were observed or reported. The laboratory at the local facility maintains and monitors the testing and reliability of the Vitros 950-chemistry analyzer. The maintenance was performed by the biomedical equipment department and is dictated by recommendations of Ortho-Clinical Diagnostics (Ortho-Clinical Diagnostics, 1998) and local laboratory policy. Machine analyzer malfunctions were not observed or corrected by the laboratory.

Limitations

The size and position of the IV catheter will had an effect on this study. Generally the smaller the size of the catheter the more difficult the blood draw which resulted in less success with the sample, this was also previously noted in other studies (Kennedy et al., 1996; Fincher, Strong & Jackson, 1998). When drawing blood from a vessel the size of the catheter directly affected the amount of blood return. If the diameter of the vessel is not adequate to hold the needle, or the pressure withdrawing the blood is too great, the vessel seemed to collapse around the needle preventing any blood from escaping. Additionally, the placement of the device on the patient was noted to have a similar effect. This caused infrequent difficulty in retrieving specimens. When retrieving the specimens it is important to note that various companies make different size IV tubing. In order to leave the IV system closed while performing this study, the blood draw occurred from the proximal hub to the patient. The length of this tubing did vary slightly. Specifying a five cubic centimeters (ccs) blood discard and using standard wasting procedures controlled this (Himberger & Himberger, 2001).

The purpose of establishing an IV is for fluid and hydration therapy. The various fluids and medicines infused through IVs could potentially taint the laboratory results

drawn from that site. This study did not control for various solutions or medicines infusing, following the study design of Himberger and Himberger (2001). Instead, the solutions and content were documented and observed for effect.

Patients present to the hospital for care related to illness. It is anticipated that any illness will have a system wide effect on blood values. There may be a rare case, such as a tumor, that may have had a stronger effect on the blood values of one area of the body. Although these values would equalize throughout the circulation, there was the potential for measurement error if retrieved from one of these areas. It was not possible to anticipate this condition and no attempt to control this variable was made.

Data Collection and Analysis

In order to replicate the study by Himberger and Himberger (2001) data collection for this study was collected through an emergency room. The sample population was one of convenience and diversity. The demographics of the sample population varied greatly. This also provided the opportunity to access patients that sought care for variety of disease processes, received different IV therapies which offered a vast quantity of data, similar to that previously collected.

The agreement analysis technique (Bland & Altman, 1995) was used to analyze the data for four reasons. First, this was the method used by Himberger and Himberger (2001). Second, the patients served as their own control. Third, a phlebotomy draw occurred simultaneously with an IV draw. Fourth, the analysis allowed the comparison of the two specimens against one another. There is an allowable variation from a specimen when sampled twice on the same machine. This method also controlled for

false elevations and depressions in readings by using the patient's own blood as reference rather than preset values from the laboratory or a group of providers.

CHAPTER II: LITERATURE REVIEW

Background

The purpose of this study was to replicate and extend prior research on the reliability of baseline laboratory blood values obtained from PIV lines (Himberger & Himberger, 2001). The literature review was inclusive of all literature from 1970 to the present. Primary sources were located and then utilized for secondary sources of literature to ensure a thorough review. Due to limited studies performed in this specific area, citations include classic studies as far back as 1983. Chapter Two addresses the various areas of previous research that was considered influential to this study. These areas are titled laboratory standards, the effect of infusing solutions and catheter devices, central venous devices, discard volumes, and established procedures for specimen collection.

Laboratory Standards

Federal guidelines set the maximum allowable analytical error by a laboratory in the Clinical Laboratory Improvement Act (CLIA) (United States Department of Health and Human Services, 1999). These guidelines are national standards used to ensure laboratories are functioning within acceptable analysis limits. Proficiency Test Providers supply anonymous samples to laboratories to test, and the results are reported to the College of American Pathologists (Chemistry Resource Committee, 1999; Hematology and Clinical Microscopy Resource Committee, 1999). Certification is mandated for any laboratory “that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of; or the assessment of the health of; human beings” (United States Department of Health and Human Services, 1999). Not only do these guidelines

set maximum level of specimen error, they address quality control measures by stating the maximum variability of the same specimen analyzed twice on the same machine. The Military has also developed a Department of Defense (DOD) Clinical Laboratory Improvement Program (CLIP)(Armed Forces Institute of Pathology, 1996) that is intended to function for Department of Defense laboratories in order to ensure they meet the requirements of the 1999 CLIA. This document maintains the same standards for maximum allowable analytical error for military laboratories. The hypotheses of this project were based on the maximum analytical error standards set by the CLIA, and the DOD CLIP, as evaluated from the Proficiency Test Providers and the College of American Pathologists (1999). The hypotheses were measured using this maximum allowable analytical error as criteria and evaluating the sampling results using the agreement analysis technique as describe by Bland and Altman (1995).

The Effect of Infusing Solutions and Catheter Devices

Research in the past has concluded that it is possible to draw a reliable sample from an infusing IV line (Herr, Bossart, Blaylock, Kroger, & Ash, 1990). This study included analysis of CBCs and chemistries, however, the authors limited the infusion volume of the IV to 100 ccs prior to specimen collection, and limited the patient population excluding the patient deemed “too ill.” A total of 38 patients were enrolled with only a 79% successful sample aspiration rate through an 18-guage IV. They reported an inability to fully aspirate five patient specimens and hemolysis of three patient specimens, establishing concern related to their method of collection. Herr and associates concluded that obtaining blood through IVs was “technically feasible and clinical accurate method of determining basic laboratory analytes... during infusion of

NS, LR, and D5W, providing the infusion is halted for two minutes.” (Herr et al., 1990, p. 791). Additionally, the type of infusing solutions resulted in no significant effects on the results of the blood count and chemistry values following a 5 cc waste of blood. Other studies support obtaining blood samples from intravenous lines with maintenance solutions infusing. Himberger and Himberger (2001) studied patients with various fluids infusing. These fluids, normal saline, lactated ringer, and dextrose 5% in water, resulted in no change in laboratory values regardless of the volume of solution infused. Additionally some of the infusions contained various medications, which also had no effect on laboratory values. Only 10% of the IV specimen sampling data were lost, due to an inability to obtain blood from the IV site. Another study (Clapham, Willis, & Maple, 1987) evaluated blood discards and concluded that following an initial discard of blood, accurate results from central venous lines as well as arterial lines could be obtained. This study evaluated the volume of discard necessary to ensure accurate arterial blood specimens based on biochemical indices taken from a 10 cc discard in five patients. Clapham and associates concluded that a 4 cc discard was necessary in order to ensure no contamination of the actual laboratory specimen from the saline/heparin solution used to maintain patency of the line.

Investigation has indicated IV rehydration and resuscitation can significantly effect the value of Hgb and Hct in healthy non-bleeding subjects (Greenfield, Bessen, & Henneman, 1989). Greenfield and associates studied 28 volunteers divided into a control group and six test groups. They proceeded to bolus the six non-control groups and give maintenance infusions to all groups. The bolus of fluid was intravenous normal saline solution of 10 ml/kg, 20 ml/kg, and 30 ml/kg dependant on the group, while the control

group received 5ml/kg/hr of normal saline for 220 minutes. Hgb and Hct sampling was obtained at the initiation of the bolus, 20 minutes, 40 minutes, and hourly for three hours. The results were then compared to a baseline Hgb and Hct drawn prior to IV initiation. Although this study concluded that there was a significant dilutional effect, Oman (1995) cites that the values of the Hgb and Hct as an indicator of bleeding in patients exposed to trauma is accurate regardless of IV hydration and resuscitation. She concluded that although there was a noted dilution in the values of the Hgb and Hct, they still accurately reflected blood volume status.

Additional research supports utilizing peripheral lines for analyte values with the exception of glucose (Ong, Boykin, & Bamett, 1979). Ong et al. studied 15 patients with intravenous lines. Samples were obtained from the non-intravenous arm and from a site in the arm with the IV, distal to the catheter insertion point. They analyzed 18 serum constituents using the standard deviation of the difference between the two specimens, the bias, and the *t* test. Ong and associates concluded that there was no clinically significant difference between the specimen drawn distally to the IV and the specimen drawn in the non-IV arm, with the exception of glucose. This value was found to be erratically elevated in subjects that had an IV infusion of dextrose. Watson, O’Kell, and Joyce (1983) collected specimens from 18 volunteers after the subjects had received 30 minutes of continuous intravenous infusion. They concluded that even after cessation of IV fluids for two minutes, if a specimen is collected above the site of an infusing IV, there is always a dilutional effect. All of the studies performed to date have either collected the specimen in an arm without an IV, from the IV itself following cessation of fluids, or distal to the IV site with the exception of Himberger and Himberger (2001).

The research that has been conducted evaluating the effects of IVs on laboratory values has randomly experimented with different specimen collection times following the discontinuance of IV infusions. A study performed by Read, Viera, and Arkin (1988) evaluated 24 volunteer subjects for specimen contamination. They obtained baseline values prior to IV initiation, began an intravenous infusion for 20 minutes, and collected specimens prior to discontinuing the infusion, at 1, 2, and 3 minutes post infusion. Their results indicated that there was no significant contamination of most analytes anywhere from one to three minutes, but a period of three minutes is encouraged to ensure that there is no significant contamination of all analytes. Watson and associates (1983) suggests two minutes is an ample time to ensure no contamination of most specimens, with the exception of patients receiving an infusion of glucose. Himberger and Himberger (2001) stopped flow of the infusion for 30 seconds followed by placement of the tourniquet proximal to the IV, and then waiting an additional 30 seconds prior to specimen collection. They reported interchangeable results of laboratory values.

Langlois and Gawryl (1987) used comparative analysis of blood specimen sampling obtained from central venous lines, arterial lines, and phlebotomy to demonstrate consistent complement activation within the samples. They had noted that complement activation had been detected in patients with similar access devices as the central venous catheters and arterial lines. This raised concern of contamination of these specimens. They studied 27 patients with simultaneous blood sampling from an arterial line, central venous catheter, and antecubital phlebotomy at time intervals from 15 minutes to 3 hours. The results of this study indicated equal complement activation from

vascular access devices and phlebotomy, validating the reliability of these devices in obtaining blood specimens.

Central Venous Devices

The use of a central venous access device is widely accepted as being an acceptable method of obtaining blood specimens, specifically in the critically ill and intensive care units (McAfee, Garland, & McNabb, 1990). Viall (1990) also supports the use of central venous lines in critical care areas to access and obtain blood specimens, particularly in patients requiring frequent laboratory tests, multiple infusions, and special nutritional needs. She also states the convenience of the central venous line in the patient with poor peripheral access, but reinforces the need to maintain strict adherence to protocols and standards. The studies that evaluated the reliability of central venous lines, and arterial lines have made recommendations regarding the discard of various amounts of blood prior to specimen collection, however, there is not a standard recommendation of the amount of discard volume.

Keller (1994) studied the use of central venous catheters as blood collection methods in bone marrow transplant patients. Her study evaluated 34 pediatric bone marrow transplant units through mailed questionnaires to providers that collected blood specimens. She found that three predominant methods of blood specimen collection were used to obtain samples through the central venous catheters of pediatric transplant patients. However, there was not a defined procedure for blood discard volumes prior to obtaining the specimens through central venous catheters, although this was standard of care for the facilities polled. These studies demonstrate that the practice of obtaining

blood specimens from intravenous lines is currently being performed, however, there is no standardize methodology for these procedures.

Discard Volume

When obtaining specimens for laboratory studies, it is crucial that the specimens are not contaminated. Contamination alters the blood values and could result in inappropriate therapies being administered. It was concluded that when using a peripheral intravenous line for specimen collection, a 5cc blood discard resulted in interchangeable values when compare to phlebotomy (Himberger & Himberger, 2001). Although numerous studies have been conducted on the use of central venous and arterial lines in obtaining blood specimens, all of the studies have indicated various amounts of blood discard prior to obtaining the actual laboratory sample (Keller 1994; McAfee et al., 1990; Viall, 1990). Arrants and associates evaluated 11 subjects for coagulation values of blood sampled from an infusion device maintained by heparin (Arrants et al., 1999). They compared blood specimen values obtained form heparin locks following a discard of 0.5 ccs of blood, 2.5 ccs of blood, and values obtained by traditional venipuncture. They concluded that following a blood discard of 0.5 ccs of blood there is no difference ($p < .001$) in specimens when compared to specimens following a 2.5 cc discard, and venipuncture. Another study (Clapham et al., 1987) evaluated various discard aliquots from 2 ccs to 10 ccs in 2 cc increments. There was no significant ($p > 0.1$) difference in the specimen results, following a 4 cc discard, but there was a difference after just 2 ccs. Yucha and DeAngelo (1996) studied nine healthy volunteers evaluating the dead space of heparin locks. Once the dead space was determined, the heparin locks were flushed with heparinized saline, and Hct values were drawn three times at ten-minute increments.

It was determined that after a 3 cc waste, using 95% confidence intervals, there was less than 1% difference in the true Hct, obtained from venipuncture, and the heparin lock specimen. Still other studies recommend 5 ccs as an appropriate discard volume (Silwa, 1997). Silwa evaluated Hct values of 29 trauma patients at admission, 1 hour, and 3 hours post intravenous fluid therapy. The specimens were drawn following a standard 5cc blood discard. She concluded that “Use of a saline lock device rather than venipuncture for serial hematocrit determinations on trauma patients is an appropriate strategy yielding accurate results with less discomfort to the patient” (Silwa, 1997, p.231). Even with a blood discard, analyte levels drawn from the heparin lock have been found to vary when compared to venipuncture. A study of 53 patients with either 18 gauge or 20 gauge IVs was conducted in which a 10cc specimen was obtained following a 3cc blood discard (Fincher et al., 1998). Specimens were obtained 78% of the attempts with an 18 gauge IV but only 60% of the attempts with a 20 gauge IV. They found that the Hgb results, when compared to phlebotomy specimens drawn from the same patients, were interchangeable. However, the potassium results showed variability, indicating this method of sampling was not reliable when evaluating potassium. Powers (1999) evaluated 32 patients with heparin infusing. Specimens were collected from a heparin lock not being used for the infusion of heparin. She evaluated coagulation studies at various discard amounts (0, 2, 4, and 6 times the dead space) and found if there is no discard prior to specimen collection, there was a 15% elevation in the coagulation values, indicating contamination of the specimen.

It is hard to distinguish what is an appropriate volume of blood to discard. It varies depending on any infusing or maintenance solution, the device being used, and the study being evaluated.

Procedures for Venipuncture Specimen Collection

In addition to the discarding of blood and cessation of infusing fluids, it is important to note proper procedures for venipuncture specimen collection. Guidelines from the National Committee for Clinical Laboratory Standards establish proper procedure when drawing blood from the area of an IV (Paulson-Happel, 1991). The committee suggests the potential for error exists even when drawing a discard specimen from an IV, and that it should be documented that the source of the specimen was associated with an IV. This methodology will alert the lab to possible erroneous results. Additional protocol standards are in place in the Air Force that direct proper procedure for venipuncture and specimen collection (United States Air Force, Technical Training Procedure Guide, 1996).

Investigation has shown the smaller the IV catheter used to obtain the blood specimen, the higher the incidence of hemolysis of the specimen (Fincher et al., 1998; Kennedy et al., 1996) resulting in lost data. Kennedy and associates evaluated 165 patients in two groups. Group A consisted of 87 patients who had an established IV. Group B consisted of 78 patients and was the control group using venipuncture for specimen collection. A total of 13.7% of the draws attempted by IV were unsuccessful due to hemolysis, compared to 3.8% hemolysis rate among the control group. They tested 6 different gauge catheters and documented the hemolysis rates experienced with each one; 24 gauge catheters (100%), 22 gauge catheters (25%), 20 gauge catheters (15%), 18

gauge catheters (10%), 16 gauge catheters (0%), and 14 gauge catheters (0%).

Interpretations of data suggest that there would be a better success rate drawing blood specimens using larger catheters. Himberger and Himberger (in press) used only 20 gauge or larger IVs and had no documented hemolysis at the time of draw but did experience three questionable analyte values which were suggested to be the result of hemolysis. This indicates only IV catheters that are 20 gauge or larger should be included in the study. It is important to note carbon dioxide levels have been found to vary during this type of research (Herr et al., 1990; Ong et al., 1979). Both studies concluded that this is most likely a false result due to transferring specimens to collection tubes or inadequate filling of specimen tubes.

Summary

A wide range of research has been conducted focusing on blood sampling with central lines, heparin, and saline locks. The samples studied have predominately focused on limited blood values such as the Hgb and Hct, although chemistry values were sampled in some studies. The study by Himberger and Himberger (2001) evaluated a wide range of blood values. The reported results were suggestive that an intravenous line specimen collection could be used interchangeably with phlebotomy specimen collection methods. Replication of their study would either validate or dispute those findings. If their findings can be repeated then it may be possible to consider a shift in the paradigm of blood specimen collection methods, expediting and improving patient care. Nurses have a pivotal role in the improvement and advancement of patient outcomes if it is determined that utilizing pre-established IV lines, regardless of solution and volume infused, is a safe and reliable method of obtaining blood specimens. This method of

sampling would improve the health outcomes of patients by expediting their care and increasing the comfort of treatment.

CHAPTER III: METHODS

Research Design

This study used a quasi-experimental design to study the research hypotheses. A control group was not used. Instead a convenience sample of patients was selected and they served as their own control. It is not possible to further describe the type of quasi-experimental design because it does not fit into any specific category as described by Burns and Grove (1997). There are some elements of a correlational design in this study, however, due to the randomization of the subjects this design is not suited for the study. Additionally the study is attempted to show that there is a lack of causality between laboratory specimen results and patient treatment. It would be inappropriate to test these hypotheses in a non-experimental design.

Sampling and Setting

The original study by Himberger and Himberger (2001) was conducted at a Level I Trauma Center in the Southwestern United States enrolling 64 patients into the study. A Level I Trauma Center is a facility that is able to accept any emergent patient, regardless of extent of injury, and have all medical subspecialties in house and available for patient care. This study used the Emergency Room at Malcolm Grow Medical Center following letters of support from the Flight Commander of the Emergency Department, and the Flight Commander of Laboratory Services. The Judge Advocate General was also consulted to ensure all legal issues area addressed. Although this Emergency Department does not offer Level I service, it does offer an annual census of approximately 40,000 patients per year, including trauma patients. This patient population is large enough to offer a diverse subject population for the study, a sample

large enough to allow for randomization, and a variety of medical illnesses allowing for broad generalization of the results. The sample size was 30 subjects.

Following approval of the Institutional Review Boards of both the Uniformed Services University of Health Sciences and the 89th Medical Group Malcolm Grow Medical Center the study commenced. Subjects were identified by Emergency Room staff and reported as potential subjects to the principle investigator. A short inquiry was made to the attending physician as to the reason for the visit and intended therapies. Once a subject was verified as a potential participant, the presenting and treating factors were considered and if the exclusion and inclusion criteria were met, the subject was approached for informed consent. The inclusion and exclusion criteria that follow, were the same criteria that was used by Himberger and Himberger (2001). These criteria have not been modified and are appropriate to this setting and sample.

Inclusion Criteria:

- a) Patients requiring IV therapy/hydration
- b) English speaking
- c) Patients with a minimum of 100 ccs of volume infused
- d) Patients that were capable of giving informed consent
- e) Any ethnic/racial group that met the above criteria

Exclusion Criteria:

- a) Patients with an IV catheter smaller than 20 gauge
- b) Patients with bilateral IV sites

- c) Patients with signs and symptoms of thrombophlebitis at the IV site at the time of study enrollment
- d) Patients suffering from hemorrhagic shock with a systolic blood pressure less than 90
- e) Patients under the age of 18

The sample size of 30 subjects was reviewed with a statistician who determined that this sample size achieved a power of .80.

Measurement Methods

The principal investigator (John R. Himberger) performed subject enrollment, informed consent, and specimen collection from the PIV. The phlebotomy specimen collection was achieved by either a registered nurse or a military medical technician using Air Force protocols established for medical technicians during phase I and II of their training (United States Air Force, 1996).

Table 1 describes the type of medical supplies that were used to complete this study.

Refer to Appendix A for the Project Cost Summary.

Table 1

Medical Supplies, Descriptions and National Listing Stock Number (NLN)

Item Name	Description	NSN Number
Purple Top Tubes	2 cc EDTA Vacutainer Plus	6640L220059
Red Top Tubes	7cc Vacutainer Plus Clot tubes	6630001451137
20 Gauge Needle	B-D Precission Glide 1 1/2 inch	6515007542836
18 Gauge Needle	B-D Precission Glide 1 1/2 inch	6515007542834
10 cc Syringe	B-D Luer-Lok 10 cc syringe	6515009824206
Alcohol Pad	Kendall Webco 2 ply 70% Pad	6510007863736
Betadine Pad	Clinipad-Iodphor PVP	6510013935154
2X2 Sterile Dressing	Kendall-Curity	6510000584421
Torniquet	1 Inch Flat Rubber	6515013826036
Hypoallergenic Tape	1 Inch Wide Silk Dermicel	6510009268882
Laboratory Bags	Biohazard Transportrac Bags	6530L4024002
Large Latex Gloves	Qualitouch Powder Free	6515L8131003
Bacteriostatic Saline	Normal Saline Multi-use Vials	0074196607

Once signed consent (Appendix B) was obtained from the subject a study data sheet (Appendix C) was completed including the subject's age, chief complaint, IV solution, and amount of solution infused. The proximal hub of the IV was identified on the IV tubing as well as the type of IV tubing being used. Malcolm Grow Medical Center was currently using IVAC Medical Systems needleless tubing with two-way Smartsite™ check valves. This allowed for the connection of a luerlock syringe directly to the port, which released a check valve allowing direct access from the syringe to the IV tubing

without the use of a needle. If the patient was received from the local emergency medical systems, traditional tubing may be used requiring the use of a needle to access the line. At the same time the antecubital phlebotomy site was identified. Both sites were cleaned with betadine followed by alcohol, to ensure all the betadine was removed. The IV was then be stopped for thirty seconds, at which time a tourniquet was applied proximal to the IV, and proximal to the phlebotomy site.

Thirty seconds after the tourniquets had been applied a 5cc waste was obtained from the IV site by attaching a luerlock syringe to the proximal port to the IV catheter or by inserting a 10cc syringe and 18-gauge needle up to the hub in the proximal port. This allowed a total of one-minute cessation of fluids prior to waste and specimen collection. Based on prior research and the goals of this study, the determination was made to use the shortest demonstrated time interval from cessation of fluids to draw. Although small waste samples have been demonstrated as providing accurate results, no study has obtained blood at this short of an interval following cessation of fluids. It has been strongly demonstrated that a 5cc waste has provided accurate results. The PIV specimen retrieval was then obtained through the IV tubing, at the closest Y port, without disconnecting the tubing from the hub. This maintained the integrity of a closed IV system and reduced the potential for infection.

The measurement of the waste sample was begun when blood was visualized entering the syringe which allowed for a standardization of the discard volume and for variances of different tubing in the distance from the Y port to the IV catheter hub. Following the collection of the discard volume the syringe was disconnected or the needle was withdrawn using negative pressure on the syringe, ensuring blood is fully

pulled back into the Y port. Blood collection of the specimen (10ccs) from the IV site were then obtained with a second 10cc luerlock syringe or a second 10 cc syringe and 18-gauge needle, again, having inserted the needle up to the hub prior to aspiration of the sample.

Following collection of the blood sample from the PIV, the IV was flushed with 10ccs of normal saline to ensure no blood remained in the IV tubing. Simultaneously a standard venipuncture specimen of 10ccs was drawn from the opposite arm. The venipuncture specimen was drawn using standard phlebotomy protocols. The sample was obtained from the venipuncture site using a 10cc syringe and 20-gauge needle. This method of specimen collection ensured standardization in the collection of both specimens. The specimens were then transferred to a 2 cc purple top adult tube and 7cc red top adult tube via 18 gauge needles to decrease the chance of hemolysis, and labeled accordingly. The specimens drawn from the infusing IV were labeled as CBC and Chemistry specimens A and the peripheral phlebotomy site were labeled as CBC and Chemistry B. All study specimens were immediately sent to the Main Laboratory for analysis under a pseudo-patient name. Any patient care samples required for treatment were drawn at a different time and analyzed accordingly, thus not interfering or delaying patient care in any manner. However, if a laboratory result were reported to be critical, the investigator in consultation with the subject's attending physician, to establish whether further patient care would have been required, would have evaluated these results.

The patients provided contact numbers for the principal investigator to report any complications to the specimen collection sites, and were instructed to do so if any concerns arise. This assisted in tracking adverse effects from the sampling technique.

The laboratory technicians were unaware of which specimens were from the PIV site and the phlebotomy site. The samples were immediately analyzed using the Main Laboratory Coulter GenS Analyzer and Vitros 950 Chemistry System. The Coulter GenS Analyzer and the Vitros 950 Chemistry system were the two analyzers being used at Malcolm Grow Medical Center's Laboratory. Both analyzers underwent routine quality control tests to ensure reliable, valid, and accurate measurements of patient laboratory values. Both sets of A and B complete blood counts and chemistry specimens were run using the same laboratory machines. The results were automatically posted from the laboratory analyzer into the hospital computer system under an investigation account. Following analysis of the specimens the principle investigator collected the results from the computer database. Should the laboratory result a critical value they would have contacted the principle investigator by phone. If he was not available they would have contacted the Emergency Department Attending Physician

In the study performed by Himberger and Himberger (2001) there were three areas of unreportable or lost data resulting in a 30% loss rate. One area was laboratory specimen testing. Almost 10% of the data from that study were lost due to laboratory error, either not completing the required test or only partially completing specimens. Another 10% of the data were lost by the laboratory failing to result entry the data to the computer system properly. The remaining area of lost data was from difficulty in obtaining blood from the patient IV or Phlebotomy site. Through clear instructions to the

laboratory and an automatic results entry system in which the specimen results are transferred from the laboratory analysis machine directly to the hospital computer, this source of lost data was eliminated. All lost data will be tracked and reported as such.

Protection of Human Rights

A standard informed consent document as shown in Appendix A was used to disclose the benefits and risks involved in enrolling in the study. The participants were provided with the option of disenrolling at any time without the fear of reprisal, repercussions, or affect to their concurrent ongoing care. A patient log (Appendix C) was maintained by the principle investigator that allowed for the correlation of data including the patient name, age, IV therapy, location, and complaint to subject number. If patients report complications after enrollment into the study the patient demographics were vital to provide follow-up care. Other wise, this document was used for the sole purpose of data analysis. The participants also had contact phone numbers that they may have called at any time should they have had any questions related to the study once enrolled.

January – December 2000

Task/Activity	Month Referenced by Number											
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>	<u>12</u>
1. Obtain IRB Approvals (MGMC/USUHS)	----											
2. Initiate Study and Data Collection*					-----							
3. Data Entry and Analysis						-----						
4. Prepare Draft Reports (MGMC/USUHS)**								----				
5. Obtain Committee Review									----			
6. Prepare Final Draft										----		
7. Hold Thesis Defense											----	
8. Make Revisions as Necessary												----
9. Obtain Signatures of Committee Members												----
10. Submit Final Reports to MGMC**												----
11. Submit Thesis for Binding/Poster Development												----

* Staff briefing regarding the study will occur during this phase of the project

**MGMC = Malcolm Grow Medical Center Institutional Review Board Reports

**USUHS = Uniformed University of Health Sciences Thesis Committee Review

CHAPTER IV: DATA ANALYSIS

Collection Factors

Data collection was completed at Malcolm Grow Medical Center following approval from the Institution Review Boards of both Uniform Services University of the Health Sciences and Malcolm Grow Medical Center (protocol #TO61BF-01). Collection occurred over a fourteen-week period. During the course of the study a selection bias did develop. This bias was directed at patient enrollment and was intentional for several reasons. First, the level of expertise of the Nurses and Technicians responsible for establishing intravenous lines varied. This provided for a subject population that was subjected to numerous intravenous attempts. The occurrence of refusal to participate was related to the number of attempts made to start an IV. The more attempts the less like the subject would consent and as a result the Principal Investigator avoided approaching these patients for enrollment. Second, due to the inexperience of the staff, there was a tendency to start 22 and 20 gauge catheters frequently. Although this study was developed to evaluate different size IV catheters, and 20 gauge catheters were included in the design, the more frequent the use of the 20 gauge catheters the more frequent potential for lost data existed (Himberger & Himberger, 2001). This would provide for less hard data to evaluate for the study. A third factor, which coexisted with the smaller intravenous lines, was that the lines were often located in awkward or difficult IV sites, following numerous attempts and again the Principal Investigator avoided this type of patient. All of these factors contributed to frequent refusals to enroll and the development of a selection bias. For a total of 30 enrolled subjects, there were 67 subject

participation refusals. Reasons for refusal were most often related to the number of IV attempts, pain associated with IV establishment, and fear of needles.

General Descriptive Statistics

The data collected was ordinal data with some serial values. The data was first entered in the Statistical Package for the Social Sciences (SPSS v. 10.0) data management software. The total number of subjects was $n=30$. However, the data on four subjects was lost and therefore calculations were conducted using $n=26$. The ages of the subjects ranged from 18 to 85 with the mean age being 47. Gender was 60% female ($n=30$) and 40 % male ($n=30$).

IV Size and Location (Lost Data)

Previous studies have noted that there is a more frequent failure to retrieve blood the smaller and more distal the IV catheters (Himberger & Himberger, 2001, Kennedy et al., 1996). During this study of the 30 subjects enrolled, 57% of the PIV used for sampling were located in the antecubital (AC), 20 % were located in the forearm, 16 % in the hand and 7% in the wrist. All of the failures to retrieve blood occurred from an AC site indicating that the distal sites were suitable for blood collection through intravenous lines. The lost data resulted from two sources. The Principal Investigator was unable to retrieve blood from the peripheral IV twice and unable to retrieve a phlebotomy specimen twice. This reflects only 7% failure of the collection procedure due to the IV site. Of the IV specimen failures, one IV was a 20-gauge catheter and the other an 18-gauge catheter. Both sites were in the antecubital area. Of the various sizes of IV catheters, 73% were 18 gauge, 27% were 20 gauge and no larger catheters were enrolled. This would indicate that of the total attempts to retrieve blood through a 20-gauge IV catheter, 12.5% of the

attempts would fail. Of the total attempts to retrieve blood from an 18-gauge catheter, 4.5% of the attempts would fail. There were no reported after effects or infections to either the IV site or the phlebotomy site following enrollment in the study.

IV Solution

The variation in IV solution available to sample for this study was relatively limited compared to that of the previous study by Himberger & Himberger (2001). The policy at the Malcolm Grow Emergency Department is to use NS for the basic solution of treatment unless special therapies or treatment is required. Thus NS was found to be the most prominent solution in study subjects ($n=28$), (93%), D5W was used infrequently $n=2$ (7%), and there were no subjects enrolled with lactated ringers IV solution.

Mean Data

Data analysis was conducted using the paired t test and correlation, and the agreement analysis technique as described by Bland and Altman (1995). Results presented in table 3 represent all of the correlative t tests. As noted, data analysis of the mean data reflects that both specimens were interchangeable, there in no significant difference ($p > .05$) in any of the values, thus accepting all of the null hypotheses.

Table 3

Paired Samples Correlations

		N	P Value	Probability of Difference
Pair 1	White Blood Cell Count A & White Blood Cell Count B	26	.989	.000
Pair 2	Red Blood Cell Count A & Red Blood Cell Count B	26	.883	.000
Pair 3	Hemoglobin Value A & Hemoglobin Value B	26	.969	.000
Pair 4	Hematocrit Value A & Hematocrit Value B	26	.970	.000
Pair 5	Platlet Count A & Platlet Count B	26	.919	.000
Pair 6	Sodium A & Sodium B	26	.864	.000
Pair 7	Potassium A & Potassium B	26	.790	.000
Pair 8	Glucose A & Glucose B	26	.999	.000
Pair 9	Chlorine A & Chlorine B	26	.944	.000
Pair 10	Bun Urea Nitrate A & Bun Urea Nitrate B	26	.997	.000
Pair 11	Creatine A & Creatine B	26	.970	.000
Pair 12	Carbon Dioxide A & Carbon Dioxide B	26	.831	.000

However, as indicated in the analysis related to proficiency testing standards (see Table 4), there were individuals who had differences in laboratory values between the two sources (PIV and venipuncture) that exceeded the values that could not be explained by the expected variance in the process of analysis (proficiency testing standards). The most concerning analyte values were the potassium results. Therefore, analysis of

individual differences was undertaken using the agreement analysis technique (Bland & Altman, 1995).

Table 4

Proficiency Testing Standards from the College of American Pathologists (1999)

Laboratory Test	N	Proficiency Test Provider Guidelines	# Exceeding Guidelines
WBC	26	+/- 15%	0/26
RBC	26	+/- 6%	3/26
Hematocrit	26	+/- 6%	2/26
Hemoglobin	26	+/- 7%	1/26
Platelet Count	26	+/- 25%	1/26
Sodium	26	+/- 4 mmol/L	0/26
Potassium	26	+/- 0.5 mmol/L	9/26
Chloride	26	+/- 5%	0/26
Carbon Dioxide	26	+/- 8% or 5 mmhg	0/26
Glucose	26	+/- 10% or >6mg/dl	0/26
Creatinine	26	+/- 15% or 0.3 mg/dl	0/26
Blood Urea Nitrogen	26	+/- 9% or 2 mg/dl	1/26

Individual Analysis

The agreement analysis technique allowed comparison of a new technique (PIV blood specimen collection) with a pre-existing technique (venipuncture) by using a 95% limit of agreement (LOA) measurement. The limit of agreement was calculated by multiplying the standard deviation by two and adding or subtracting that result from the mean of the values. This allowed comparison of the mean differences and variance of data relative to the indicators of clinical significance (95% LOA). It was possible to determine if obtaining blood through a PIV was considered interchangeable with venipuncture, using the mean value of the gold standard against the new standard. If the values of a particular laboratory study fell within the 95% limit of the agreement then the new method of blood collection using the PIV was considered interchangeable with venipuncture.

White Blood Cell Count

Analysis of individual data for white blood cell count values indicated that there was one specimen that fell outside the 95% level of agreement (See figure 1). None of the specimen pairs exceeded the Proficiency Testing Standards. Upon evaluation of the specimen pair (#11) that was outside the LOA (PIV=13.1 μ l, Phlebotomy=14.1 μ l), it was found that there was difficulty (delayed location of the vein with veinipuncture) in obtaining the phlebotomy blood for sampling. This delay could have possibly resulted in an inflammatory response to the area resulting in elevated WBC at that site.

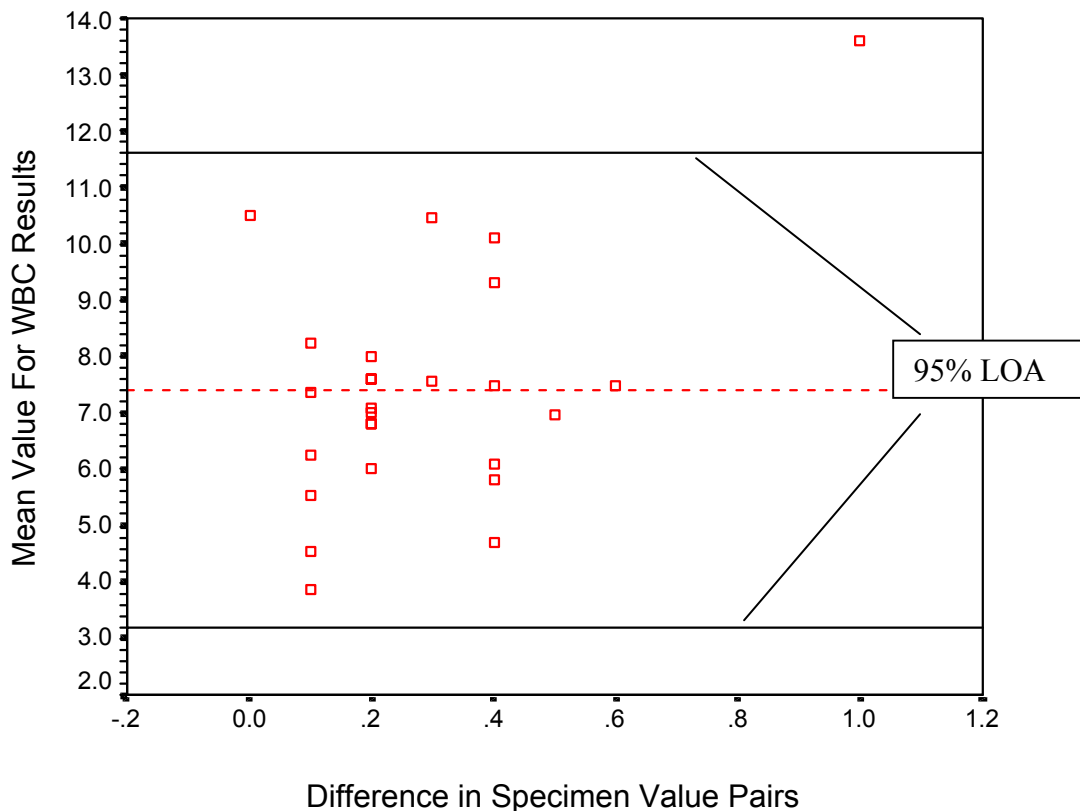


Figure 1: White Blood Cell Agreement Analysis PIV vs. Phlebotomy

Red Blood Cell Count

Analysis of individual data for red blood cell count values indicated that there was one specimen that fell outside the 95% level of agreement (See figure 2). Three of the specimen pairs exceeded the Proficiency Testing Standards (#8, 9 & 13). During collection of two of these specimen pairs #8 (PIV=4.19 μ l, Phlebotomy=4.47 μ l) and #13 (PIV=4.35 μ l, Phlebotomy=4.77 μ l), there was difficulty in obtaining the phlebotomy specimens. There was no complication while drawing specimen pair #9 (PIV=4.23 μ l, Phlebotomy=5.37 μ l). Upon evaluation of the specimen pair (#10) that was outside the LOA (PIV=3.31 μ l, Phlebotomy=3.38 μ l) there were no complications during the specimen collection.

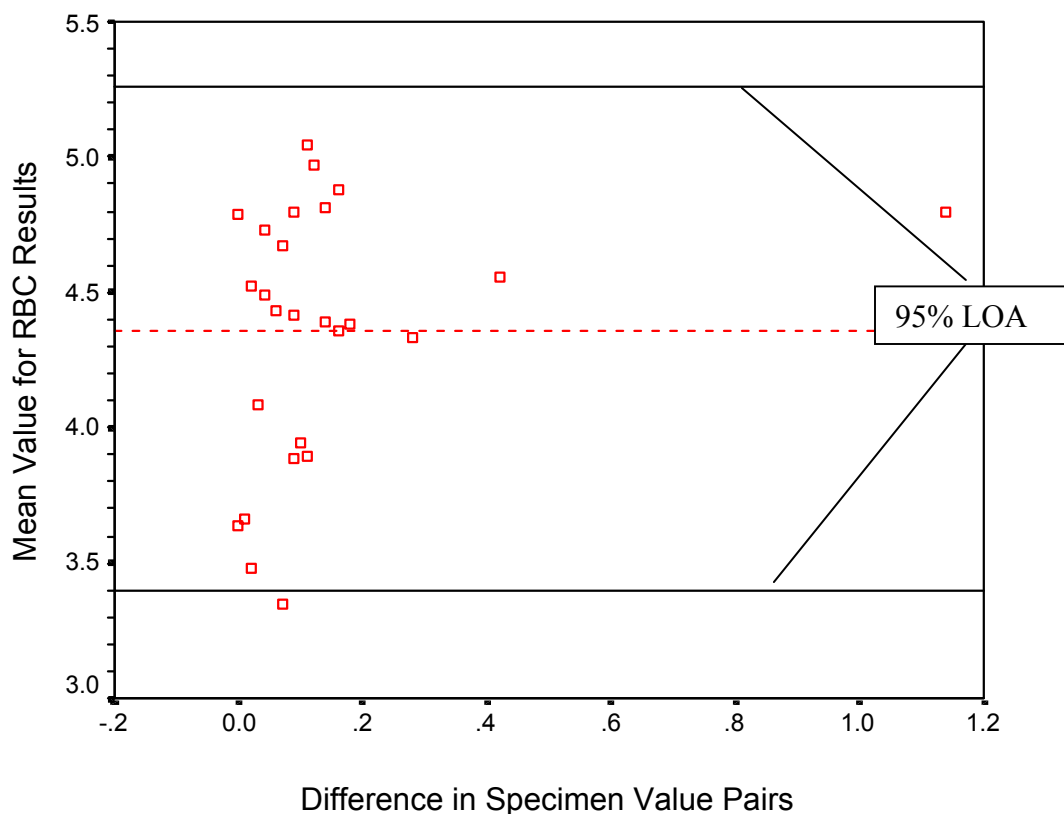


Figure 2: Red Blood Cell Agreement Analysis PIV vs. Phlebotomy

Hemoglobin

Analysis of individual data for hemoglobin values indicated that there was one specimen pair that fell outside the 95% level of agreement (See figure 4). One of the specimen pairs exceeded the Proficiency Testing Standards (# 8). During collection of specimen pair #8 (PIV=13.2g/dl, Phlebotomy=14.2g/dl), there was difficulty in obtaining the phlebotomy specimen. Upon evaluation of the specimen pair (#23) that was outside the LOA (PIV=13.1g/dl, Phlebotomy=13.5g/dl), there was a slow return from the PIV, and this specimen was retrieved from a D5W line with Ancef® infusing. In addition to this value being outside the LOA, the values for the hematocrit and glucose were also affected indicating a possible contamination effect from the medication or the D5W.

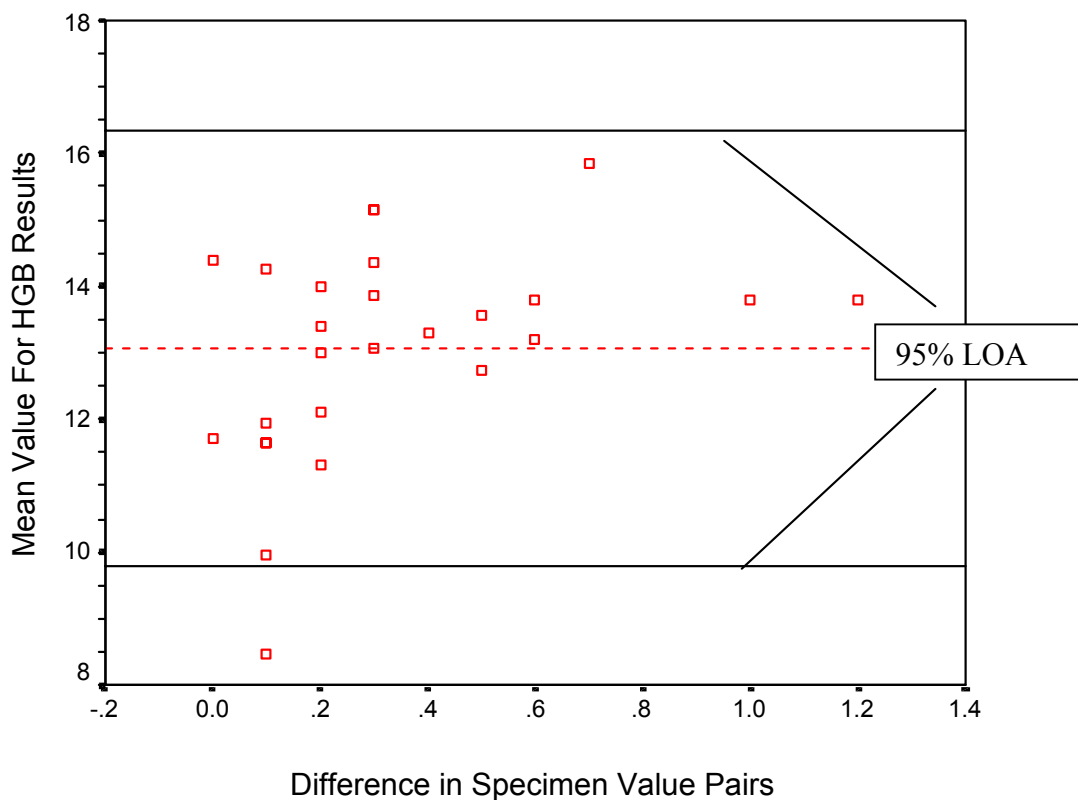


Figure 3: Hemoglobin Agreement Analysis PIV vs. Phlebotomy

Hematocrit

Analysis of individual data for hematocrit values indicated that there was one specimen pair (#23) that fell outside the 95% level of agreement (See figure 3). Two of the specimen pairs exceeded the Proficiency Testing Standards (#8 & 13). During collection of two of these specimen pairs #8 (PIV=38.2%, Phlebotomy=41.0%) and #13 (PIV=37.4%, Phlebotomy=41.0%), there was difficulty in obtaining the phlebotomy specimens. Upon evaluation of the specimen pair (#23) that was outside the LOA (PIV=26.1%, Phlebotomy=26.1%), there was a slow return from the PIV, and this specimen was retrieved from a D5W line with Ancef® infusing. In addition to this value being outside the LOA, the values for the hemoglobin and glucose were also affected, indicating either a correct physiological reading outside normal parameters or a possible contamination effect from the medication or the D5W, the first being most probable.

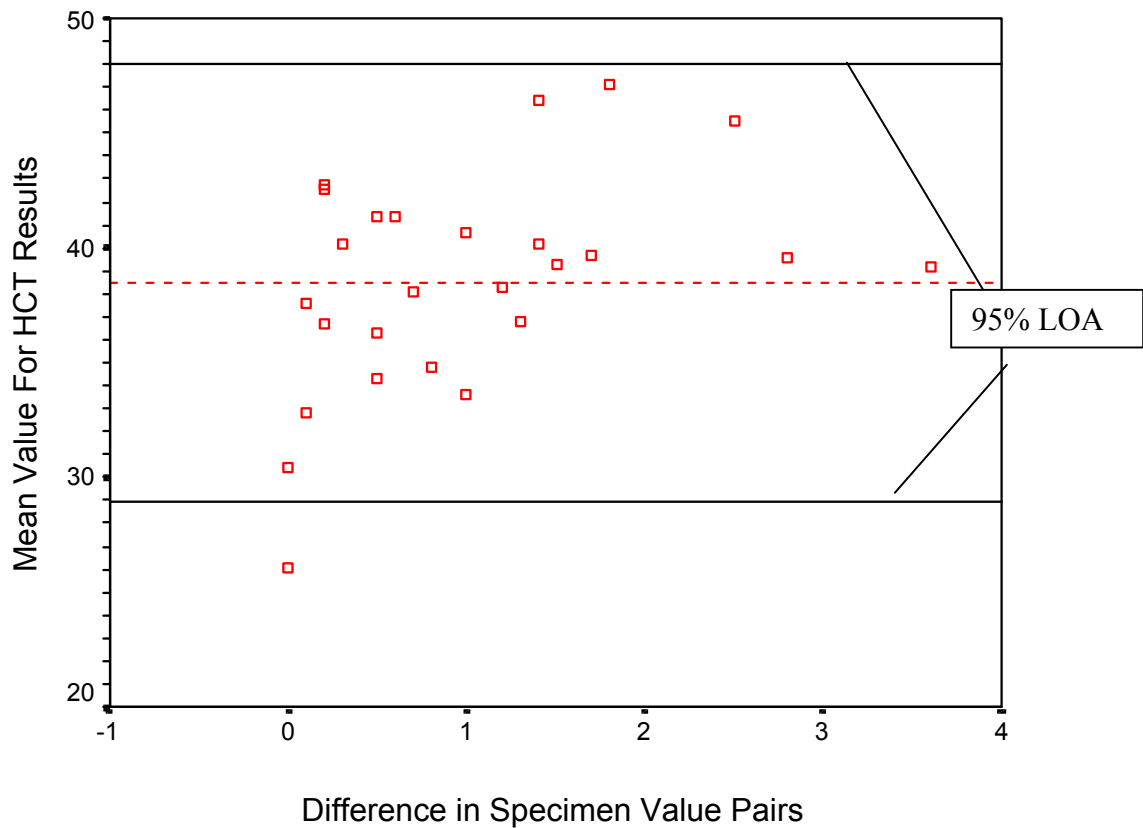


Figure 4: Hematocrit Agreement Analysis PIV vs. Phlebotomy

Platelets

Analysis of individual data for hemoglobin values indicated that there was one specimen pair that fell outside the 95% level of agreement (See figure 5). One of the specimen pairs exceeded the Proficiency Testing Standards (# 8). During collection of specimen pair #8 (PIV=202 μ l, Phlebotomy=86 μ l), there was difficulty in obtaining the phlebotomy specimen. Upon evaluation of the specimen pair (#21) that was outside the LOA (PIV=234 μ l, Phlebotomy=232 μ l), there were no complications during the specimen collection. Upon individual evaluation this specimen's results were within 2 points of each other and are considered interchangeable, there was no explanation for this result.

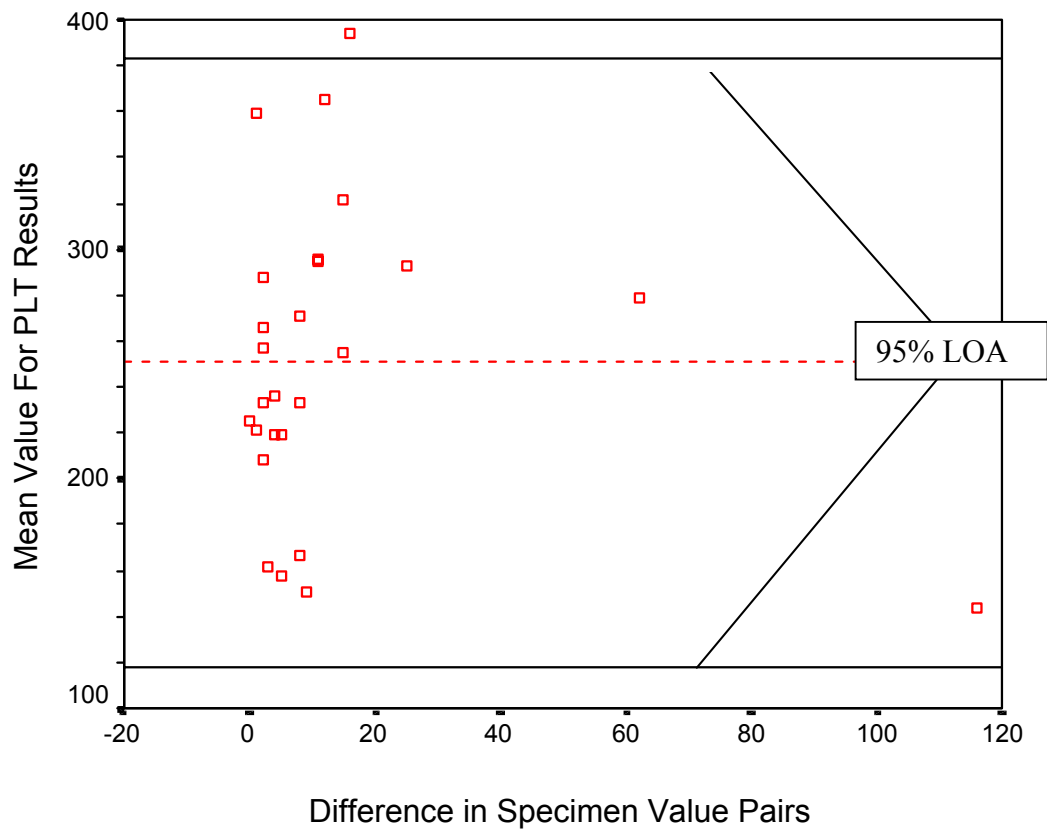


Figure 5: Platelet Agreement Analysis PIV vs. Phlebotomy

Sodium

Analysis of individual data for sodium values indicated that there was one specimen that fell outside the 95% level of agreement (See figure 6). None of the specimen pairs exceeded the Proficiency Testing Standards. Upon evaluation of the specimen pair (#2) that was outside the LOA (PIV=146mmol/L, Phlebotomy=145mmol/L), there were no complications during the specimen collection. Upon individual evaluation this specimen's results are within 1 mmol/L of each other and were therefore considered interchangeable. During the collection process there was slow return from the IV that could have possibly allowed sodium from the NS solution to contaminate the PIV specimen. In addition to this

specimen pair being outside the LOA, the results for chloride and CO₂ for the same specimen pair were outside the LOA, supporting probable contamination.

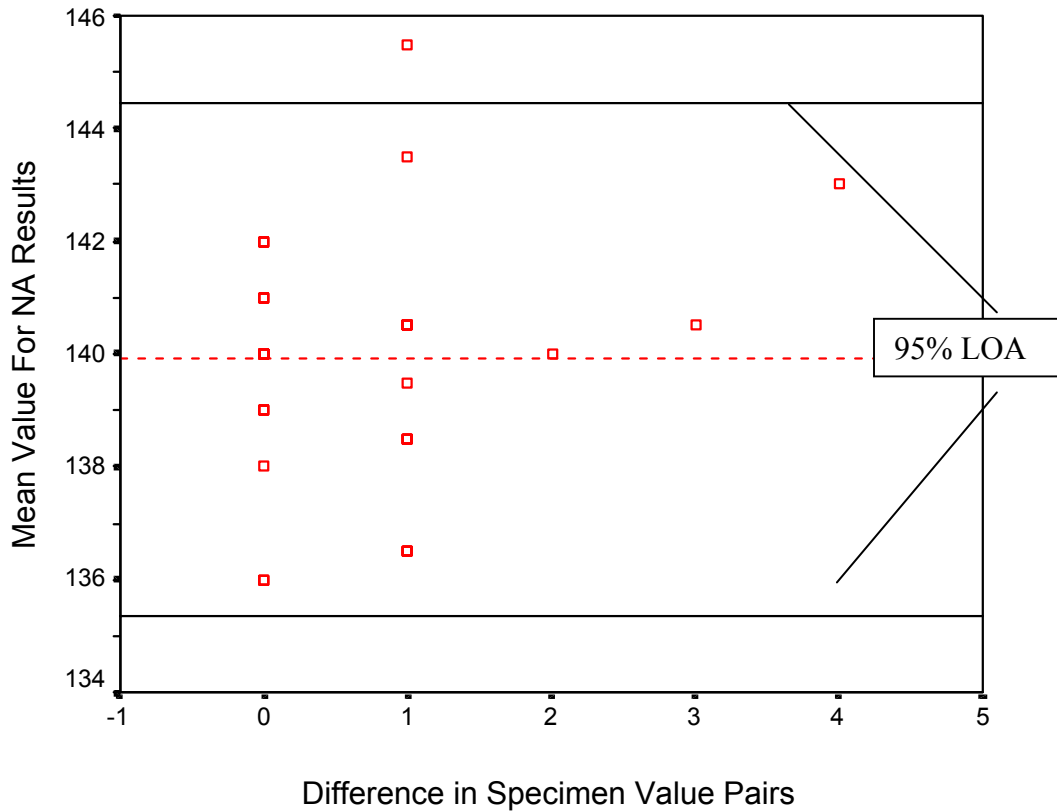


Figure 6: Sodium Agreement Analysis PIV vs. Phlebotomy

Potassium

Analysis of individual data for potassium values indicated that there were no specimen pairs that fell outside the 95% level of agreement (See figure 7). However, nine of the specimen pairs exceeded the Proficiency Testing Standards (#5, #7, #11, #15, #16, #19, #20, #23, & #26). During collection of specimen pair #11 (PIV=3.3mmol/L, Phlebotomy=4.1mmol/L), #15 (PIV=4.1mmol/L, Phlebotomy=4.3mmol/L), #16 (PIV=3.7mmol/L, Phlebotomy=3.9mmol/L), there was difficulty in obtaining the

phlebotomy specimens. In the other specimens #5 (PIV=4.2mmol/L, Phlebotomy=4.4mmol/L), #7 (PIV=4.2mmol/L, Phlebotomy=4.4mmol/L), #19 (PIV=4.0mmol/L, Phlebotomy=3.8mmol/L), #20 (PIV=3.6mmol/L, Phlebotomy=3.8mmol/L), #23 (PIV=3.9mmol/L, Phlebotomy=3.7mmol/L), and #26 (PIV=4.0mmol/L, Phlebotomy=3.7mmol/L), there were no complications during the collection process.

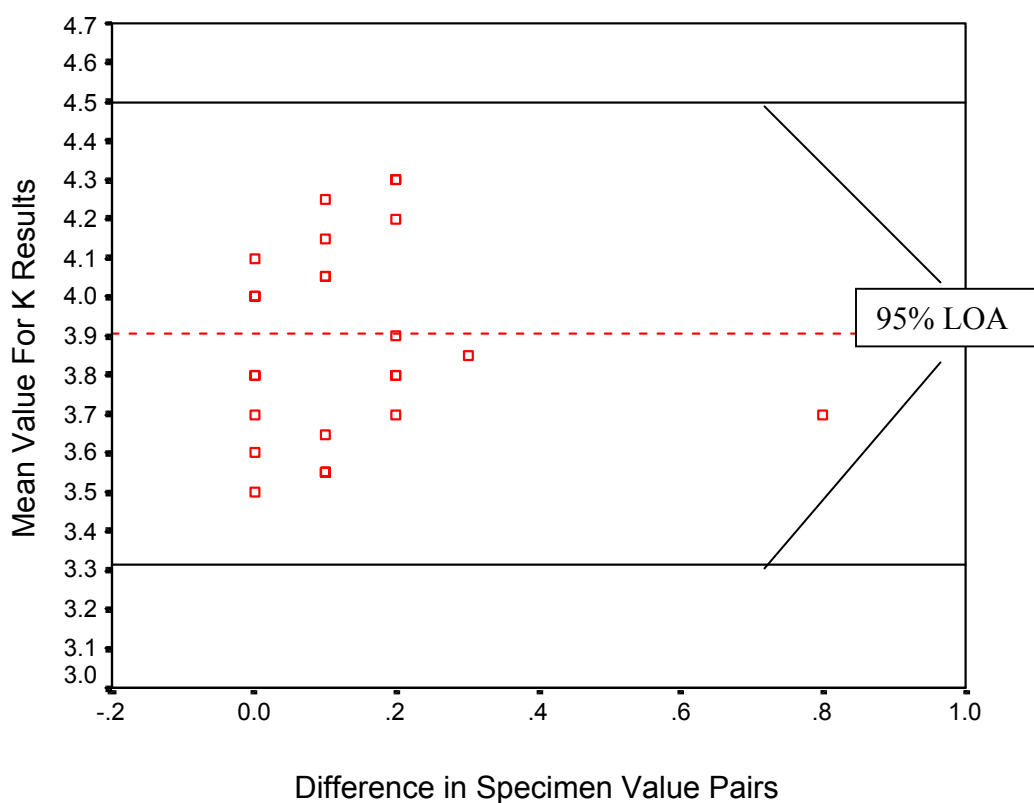


Figure 7: Potassium Agreement Analysis PIV vs. Phlebotomy

Chloride

Analysis of individual data for chloride values indicated that there was one specimen pair that fell outside the 95% level of agreement (See figure 8). None of the specimen pairs exceeded the Proficiency Testing Standards. Upon evaluation of the

specimen pair (#2) that was outside the LOA (PIV=119mmol/L, Phlebotomy=118mmol/L), this specimen's results were within 1 mmol/L of each other and therefore were considered interchangeable. During the collection process there was slow return from the IV that could have possibly allowed sodium from the NS solution to contaminate the PIV specimen. In addition to this specimen being outside the LOA, the results for sodium and CO₂ for the same specimen pair were outside the LOA, supporting probable contamination.

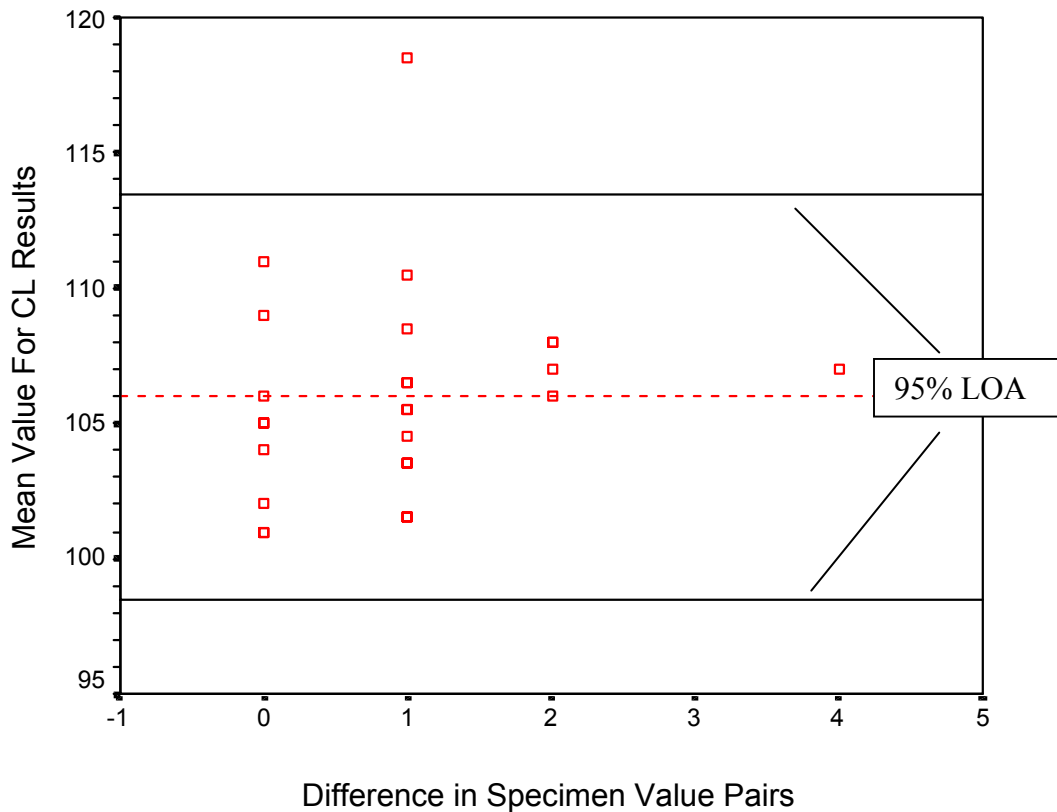


Figure 8: Chloride Agreement Analysis PIV vs. Phlebotomy

Glucose

Analysis of individual data for glucose values indicated that there were two specimen pairs that fell outside the 95% level of agreement (See figure 9). None of the specimen pairs

exceeded the Proficiency Testing Standards. Upon evaluation of the specimen pairs (#22, #23) that were outside the LOA (PIV=327mg/dl, Phlebotomy=325mg/dl, PIV=331mg/dl, Phlebotomy=315mg/dl), the specimen's results were within 2 mg/dl and 16 mg/dl of each other, respectively, and therefore were considered interchangeable. Upon evaluation of specimen pair #22, there were no complications during the collection process. Upon evaluation of the specimen pair (#23) that was outside the LOA (PIV=13.1g/dl, Phlebotomy=13.5g/dl), there was a slow return from the PIV during the specimen collection; however, the PIV specimen was retrieved from a D5W line with Ancef® infusing. In addition to this value being outside the LOA, the values for the hematocrit and hemoglobin were also affected indicating a possible contamination effect from the medication or the D5W supporting probable contamination.

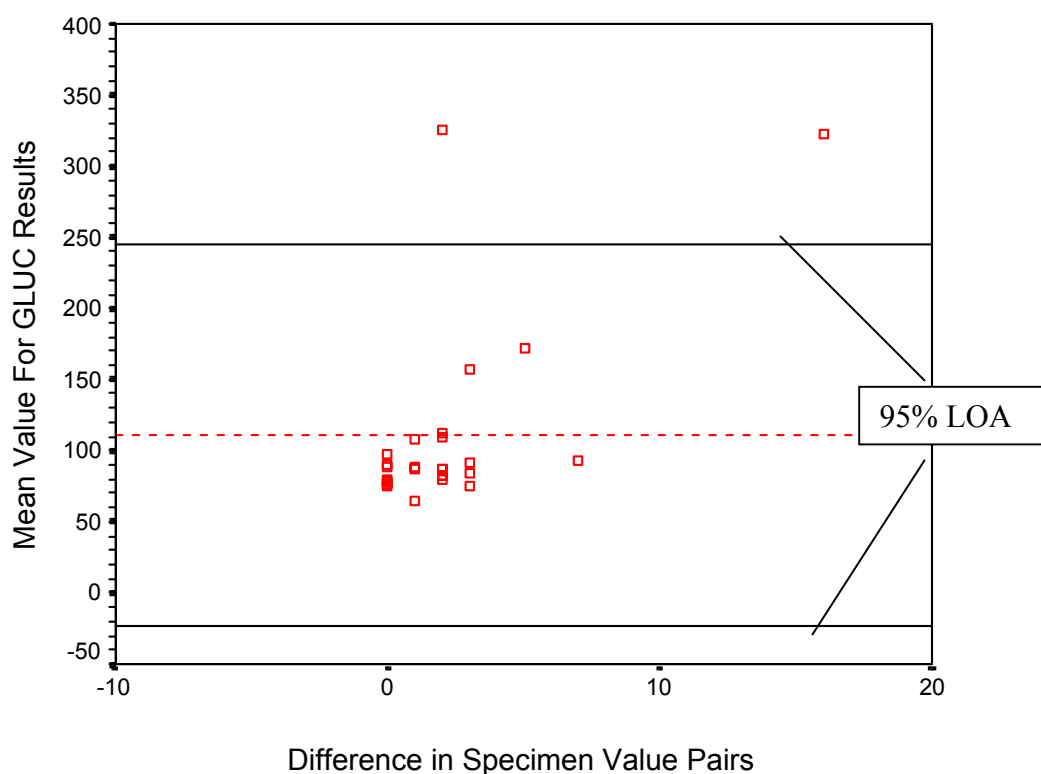


Figure 9: Glucose Agreement Analysis PIV vs. Phlebotomy

Carbon Dioxide (CO₂)

Analysis of individual data for CO₂ values indicated that there was one specimen pair that fell outside the 95% level of agreement (See figure 10). None of the specimen pairs exceeded the Proficiency Testing Standards. Upon evaluation of the specimen pair (#2) that was outside the LOA (PIV=20mmol/L, Phlebotomy=21mmol/L), this specimen's results were within 1 mmol/L of each other and therefore were considered interchangeable. During the collection process there was slow return from the IV that could have possibly allowed sodium from the NS solution to contaminate the specimen. In addition to this specimen being outside the LOA, the results for sodium and chloride for the same specimen were outside the LOA, supporting probable contamination.

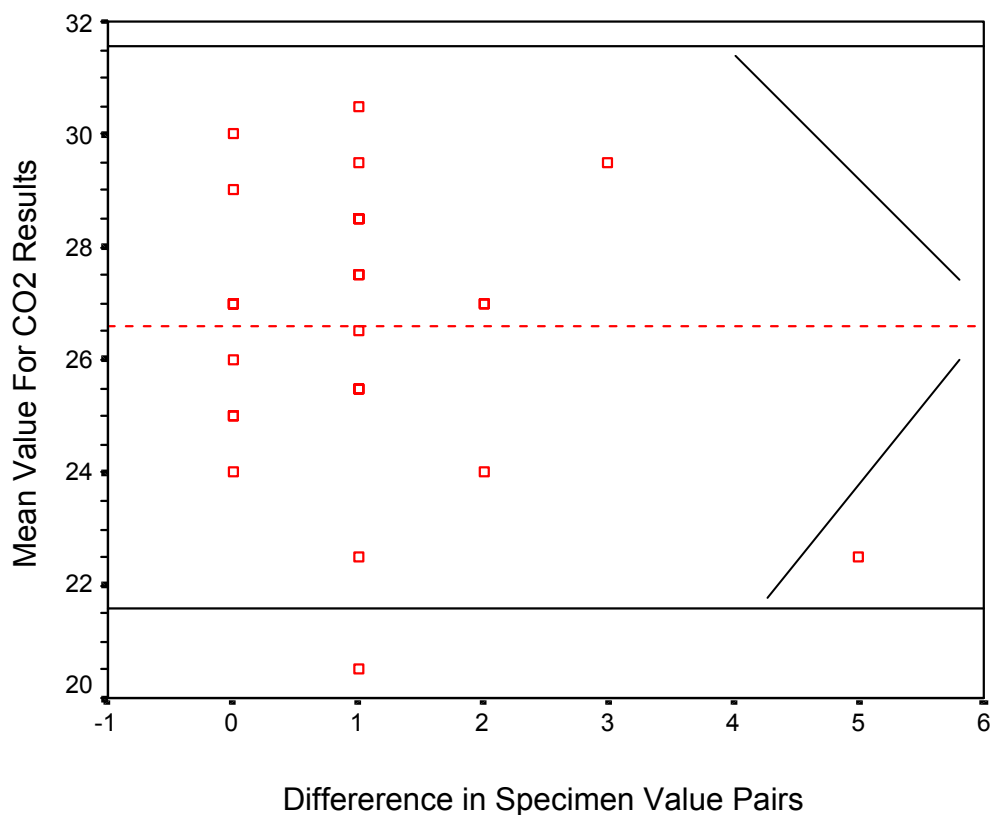


Figure 10: Carbon Dioxide Agreement Analysis PIV vs. Phlebotomy

Creatinine

Analysis of individual data for creatinine values indicated that there were no specimen pairs that fell outside the 95% level of agreement (See figure 12). Additionally no specimen pairs exceeded the Proficiency Testing Standards.

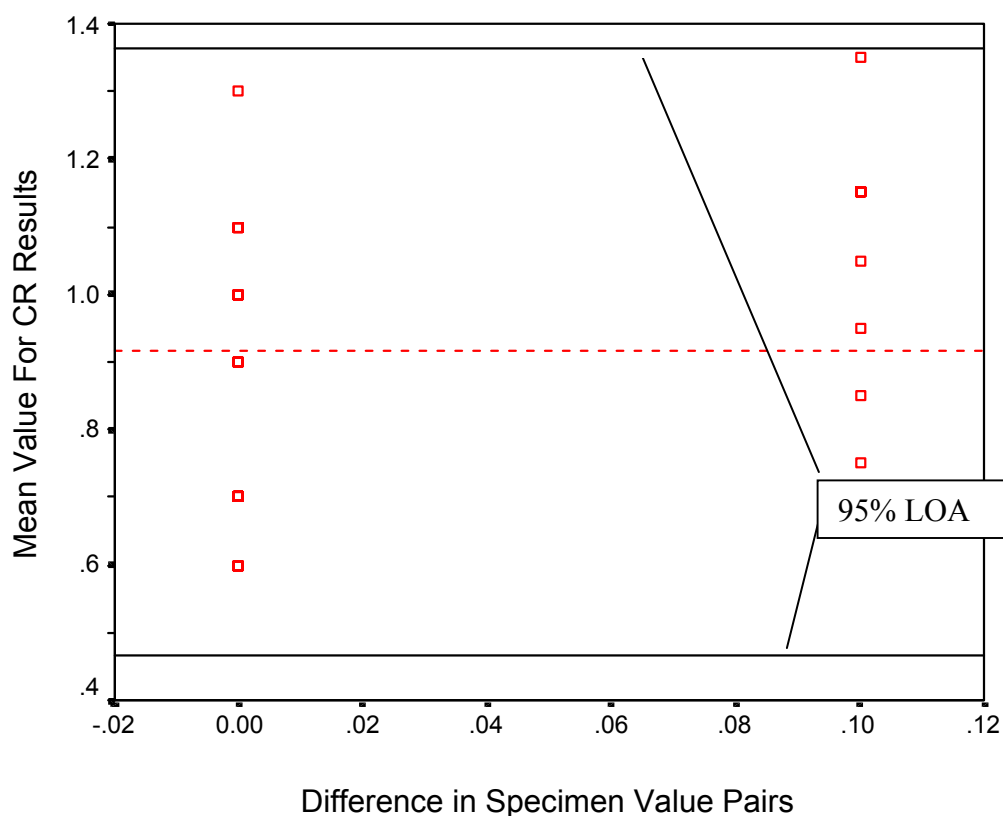


Figure 11: Creatinine Agreement Analysis. PIV vs. Phlebotomy

Blood Urea Nitrate (BUN)

Analysis of individual data for BUN values indicated that there was one specimen pair that fell outside the 95% level of agreement (See figure 12). One of the specimen pairs exceeded the Proficiency Testing Standards (# 25). During collection of specimen #25 (PIV=11mg/dl, Phlebotomy=10mg/dl), there was difficulty in obtaining the phlebotomy specimen. Upon evaluation of the specimen pair (#1) that was outside the LOA

(PIV=27mg/dl, Phlebotomy=27mg/dl), this specimen's results were equal to each other and therefore were considered interchangeable. During the collection process there was difficulty obtaining the phlebotomy specimen. However, these values were equal and this result is most likely a correct result reflecting an abnormal physiological process.

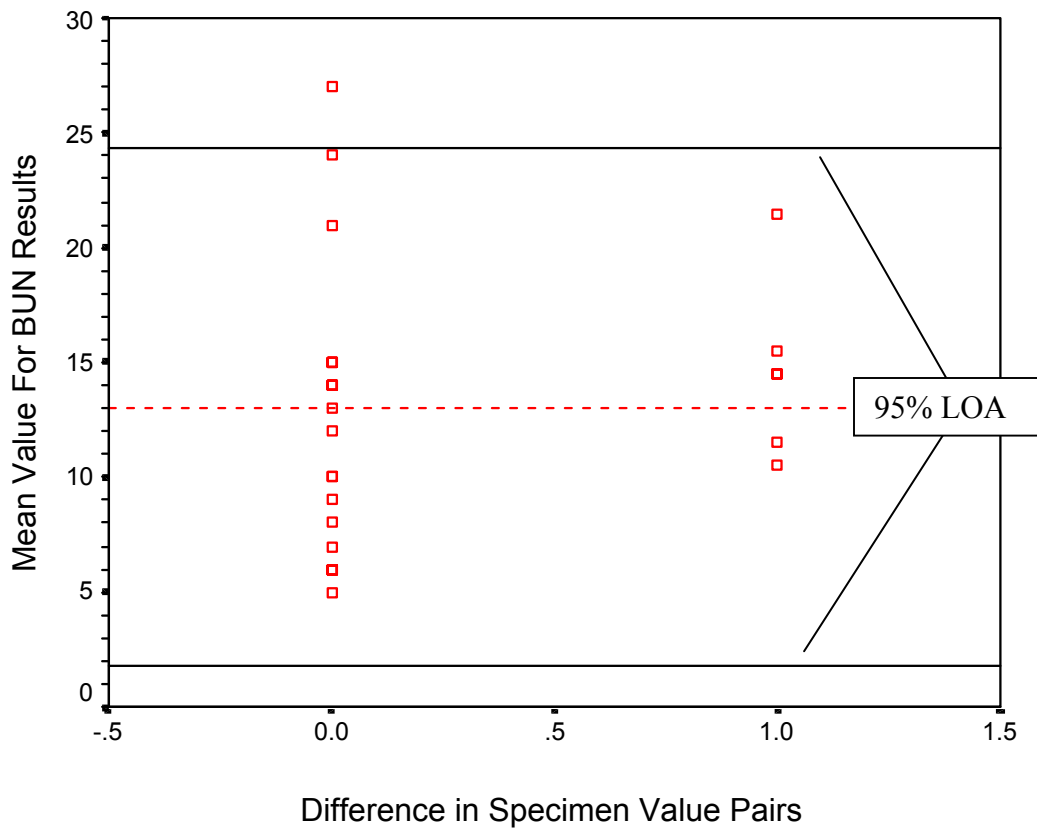


Figure 12: Blood Urea Nitrate Agreement Analysis PIV vs. Phlebotomy

Chapter V: DISCUSSION

The purpose of this project was to test the following hypotheses:

1. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 15\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in WBC counts in blood obtained from PIV compared to venipuncture.

2. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 6\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in RBC counts in blood obtained from PIV compared to venipuncture.

3. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 7\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in HGB values in blood obtained from PIV compared to venipuncture.

4. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 6\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in HCT values in blood obtained from PIV compared to venipuncture.

5. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 25\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in PLT counts in blood obtained from PIV compared to venipuncture.

6. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than ± 4 millimoles/liter difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Na values in blood obtained from PIV compared to venipuncture.

7. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than ± 0.5 millimoles/liter difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in K values in blood obtained from PIV compared to venipuncture.

8. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 5\%$ difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Cl values in blood obtained from PIV compared to venipuncture.

9. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 10\%$ or 6 milligrams/deciliter difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in Gluc values in blood obtained from PIV compared to venipuncture.

10. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than 8% or ± 5 millimeter mercury difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in CO₂ values in blood obtained from PIV compared to venipuncture.

11. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 15\%$ or 0.3 milligrams/deciliter, whichever is greater, difference using Proficiency Test Provider standards as recorded by the College

of American Pathologists (1999), in Cr values in blood obtained from PIV compared to venipuncture.

12. There will not be a significant difference ($p > .05$) using the agreement analysis technique and not more than $\pm 9\%$ or 2 milligrams/deciliter, whichever is greater, difference using Proficiency Test Provider standards as recorded by the College of American Pathologists (1999), in BUN values in blood obtained from PIV compared to venipuncture.

Of the 312 values analyzed, 5% or 16 values fell outside the range of acceptable variance according to proficiency testing standards from the College of American Pathologists (Chemistry Resource Committee, 1999; Hematology and Clinical Microscopy Resource Committee, 1999). Of these 16 values, six(38%) of the values were from the same two specimens (#8 & #13). Nine (56%) of the values were variations in the potassium results by no more than .3mmol/L, and 1 (6%) was a RBC specimen. Of the six results from the two specimens, both of were retrieved with difficulty from the phlebotomy site, indicating variation the collection process and resulting in contaminated results. Of the nine results of potassium, two of the specimens were retrieved from phlebotomy sites with difficulty indicating a degree of hemolysis. The other seven potassium results reflect that values from the phlebotomy sites are consistently elevated indicating either hemodilution of the PIV specimen or, more probable, hemolysis during the phlebotomy collection. The red blood cell specimen pair (#12) results were PIV=4.35 μ l, Phlebotomy=4.77 μ l, which were relatively close, within normal values and would not result in clinical treatment. The final analysis of these results can support a conclusion that occasional values of specimens drawn from PIV sites will vary when

compared to phlebotomy controls using the standards provided by the American College of Pathologists (1999). These results, most often potassium, would not alter a patient's clinical treatment. The individual analysis of the other analytes, Na, Cl, Gluc, C02, BUN, and Cr, and the hematological value, WBC, showed interchangeable results. Reinforcing the reliability of this technique.

The agreement analysis technique reflected that both potassium and creatinine results are within 95% LOA. The results for WBC, RBC, HCT, HGB, PLT, NA, GLUC, CL, CR, and CO2 did reflect eleven specimen pairs (3.5% of the 312) that exceeded the 95% level of agreement. However, eight of the eleven pairs were either collected with difficulty from the phlebotomy site or appear outside the LOA on more than one analysis figure, indicating contamination in the specimens. The other three specimen pairs (#10 RBC, #21PLT, & #22GLUC) exceeded the LOA, but would not result in clinical treatment. The results for all three specimen pairs were well within the parameters of the proficiency testing standards.

Conclusion

This study has demonstrated that the basic analytes (Na, K, Cl, Gluc, C02, Cr, BUN) and basic hematological values (WBC, RBC, H&H, PLT) of blood samples drawn through a PIV are interchangeable with those of basic analytes (Na, K, Cl, Gluc, C02, Cr, BUN) and basic hematological values (WBC, RBC, H&H, PLT), of a traditionally obtained blood specimen from venipuncture. Caution should be used when evaluating the results of specimens obtained using this technique to ensure that they correlate to the clinical picture that the patient presents with. The most concerning analyte would be potassium, although alterations in this value that occurred during this study would not

reflect a change in a patient's clinical care, it was the most common altered analyte found indicating a level of hemolysis during phlebotomy collection.

Additionally, during the study there were no reported or noted complications with the intravenous site from any study participants, intra or post participation, indicating this is a safe and effective method for obtaining blood specimens.

It has been noted in the past that various methods of blood collection do indeed cause varying results in the item studied. These variations "although statistically significant, are not clinically significant" (Burtis & Ashwood, 1994). The individual agreement analysis of the values in this study demonstrated and reinforced that although there were statistical differences, that difference would not change, alter, or affect the treatment of patients in the clinical setting. Treatment of patients should be based on the overall presentation of the individual case and no single laboratory result should be used exclusively to manage care of a patient. It is recommended that, as a standard fundamental principle in interpreting laboratory results, a practitioner should not rely on a single value to diagnose a patient (Henry, 1992). In fact, diagnosis should be made after a trend has been determined in the laboratory results.

The method of collecting blood specimens from infusing intravenous lines using the protocols outlined in this study are considered interchangeable based on these results, regardless of amount of solution infused. However, strict adherence to protocols is necessary to provide interchangeable results. Although this method provides reliable blood values, it is recommended that each specimen be monitored for possible contamination as reflected by numerous elevated or decreased blood values in specimens drawn simultaneously. Adoption of this method would provide the opportunity to

improve patient comfort, decrease patient exposure to infection and increase the vascular accessibility of patients suffering vascular collapse or those subject to poor vascular accessibility. This method could potentially decrease the time to critical therapies for patients, and could make the difference in saving lives.

Limitations

Although this study does answer the question of interchangeability of specimens using collection methods from a PIV vs. phlebotomy technique, there are limitations to this study that are important to recognize. The sample size was relatively small. However because this study attempted to prove the null hypotheses, the sample was of acceptable size. This study did not fully replicate the study performed by Himberger and Himberger (2001). Their study was able to distribute the sample between NS, D5W, and LR. This study was not able to enroll any subjects with LR infusing. Additionally, only one subject was enrolled with D5W infusing. Lastly, the selection bias that developed, as discussed in Chapter IV, was potentially limiting in evaluating the accessibility of different size IV catheters for this type of technique.

Opportunities for Further Research

This study answers the question of interchangeability of lab specimens drawn from an infusing PIV and those drawn using venipuncture. However answering this question offers other opportunities for study. It would be beneficial to investigate the stability of long term serial laboratory draws with infusing intravenous fluids. One of the criticisms of techniques similar to this is the frequent wasting of blood necessary to successfully obtain blood specimens. This would warrant investigation of a standard discard volume to be used with this technique. Future studies to support this data may

allow for a change in clinical practice. Only by investigating these questions can we continue to improve the care we provide to those we serve.

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APPENDICES

Appendix A - Project Cost Summary

Appendix B - Informed Consent Document

Appendix C - Subject Data Collection Sheet

Appendix D - Approval Letter from Malcolm Grow Institutional Review Board

Appendix E - Approval Letter from USUHS Institutional Review Board

Appendix F - Approval Letter from Office of the Surgeon General

Appendix A - Project Cost Summary

Project Cost Summary

Item Name	NSN Number	Cost/Item	Total Cost
Purple Top Tubes	6640L220059	7.49/100 Tubes	\$7.49
Red Top Tubes	6630001451137	7.49/100 Tubes	\$7.49
20 Gauge Needle	6515007542836	3.23/100 Needles	\$3.23
18 Gauge Needle	6515007542834	2.23/100 Needles	\$4.46
10 cc Syringe	6515009824206	7.99/100 Syringes	\$14.98
Alcohol Pad	6510007863736	1.31/200 Pads	\$1.31
Betadine Pad	6510013935154	.42/200 Pads	\$0.42
2X2 Sterile Dressing	6510000584421	2.02/50 Pads	\$2.02
Torniquet	6515013826036	4.05/1 Torniquet	\$8.10
Hypoallergenic Tape	6510009268882	6.27/Box of 12	\$6.27
Laboratory Bags	6530L4024002	5.11/100 Bags	\$5.11
Gloves Large	6515L8131003	5.40/Box of 100	\$11.20
Bacteriostatic Saline	0074196607	6.18/25 Bottles	\$6.18
Total Costs for Equipment			\$78.26

Complete Blood Count	11.80/Test	\$708.00
Chemistry	12.60/Test	\$756.00
Total Laboratory Testing Cost	\$1,464.00	

Appendix B - Informed Consent Form

INFORMED CONSENT FORM FOR THE RESEARCH STUDY

Blood Sampling Reliability Using Intravenous Lines

Principle Investigator: Captain John R. Himberger, USAF, NC

Uniformed Services University Graduate School of Nursing

(301) 295- 1001

Privacy act of 1974 applies. DD form 2005 filed in clinical/medical records.

PRIVACY ISSUES: Records of my participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 USC 552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Health Care Records, contains the Privacy Act Statement for the records. I understand that the U.S. Food and Drug Administration (FDA), the sponsoring agency and/or their designee, if applicable, may inspect records of this study. (This consent document is written in first person for those individuals completing it for their own participation in the study. The language should be considered to refer to the subject when a guardian or legal representative is completing the form on the subject's behalf. Therefore, this ICD will serve for adult or surrogate consent.)

PURPOSE AND DURATION OF STUDY

I _____(SSN)_____ hereby volunteer to participate as a test subject in this experimental research study. The purpose of this study is to evaluate the accuracy of blood tests obtained from an intravenous line site, which is an area that a plastic catheter is inserted into a vein and has tubing attached to it with fluids running.

This study will enroll approximately 30 subjects at Malcolm Grow Medical Center over the course of one year.

PROCEDURE

As a participant, I understand that I will undergo the following procedures: I will have a rubber hose (tourniquet) wrapped around both my arms for 30 seconds. I will then have my blood drawn in the routine manner (sticking a needle into a vein in my arm) withdrawing approximately 2 teaspoons of blood from my arm without an intravenous line. Additionally, using a needle and syringe, or just a syringe, depending upon the tubing type, one teaspoon of blood will be drawn through the tubing of the intravenous fluid line and thrown away followed by approximately 2 teaspoons of blood drawn for testing. The blood tests will include a blood count used to check for common infections such as a cold, blood counts to check my blood volume and ability to stop bleeding, as well as a salt level, chloride level, potassium level, sugar level, and kidney function tests. I understand that these two blood draws will be obtained solely for the purpose of facilitating this study and the results will not be placed in my medical record. Should my physician deem it necessary for me to have a procedure requiring additional informed consent, a separate informed consent document will be completed at the time of the procedure.

BENEFIT

I understand that there is no guarantee I will receive any benefit from this study, except knowing the information gained may help future patient.

ALTERNATIVE TREATMENT

I understand that choosing not to participate in this study is the alternative to volunteering for the study. Blood will still be drawn by standard venipuncture (sticking a needle in a vein in my arm) as necessary for my treatment.

RISKS OR DISCOMFORTS

I may experience bruising and soreness at the site where blood is drawn. It is uncommon based on prior research but I may develop thrombophlebitis or cellulitis (infections) at either the blood drawing site or the intravenous line site. I may also require a new intravenous site for my ongoing care if the site used for the study stops working.

ENTITLEMENT TO CARE

I understand that my entitlement to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations, and if I have questions about my rights or if I believe I have received a research-related injury, I may contact the Malcolm Grow Medical Center Patient Representative (240) 857-5817, the Director of the Clinical Investigation Facility at Malcolm Grow Medical Center, and/or the investigator Capt. John Himberger, (301) 295-1001.

I understand that participation in this study does not alter my ongoing medical benefits as a military beneficiary, and I will continue to receive any needed medical treatment should I experience illness or injury as a result of this study.

OCCURANCE OF UNANTICIPATED EVENT

I understand that any unanticipated event (clinical or medical misadventure) will immediately be brought to my attention or, if I am not competent at the time to understand the nature of the misadventure, such information will then be brought to the attention of my guardian or next of kin. In the event that a critical laboratory test is discovered it will be reported to my attending physician to evaluate and could possibly result in further medical treatment.

VOLUNTARY PARTICIPATION

The decision to participate in this study is completely voluntary on my part. No one has coerced or intimidated me into participating in this program. I am participating because I want to. Captain John Himberger has adequately answered any and all questions I have about this study, my participation, and the procedures involved. I understand that Captain Himberger will be available to answer any questions concerning procedures throughout this study. I understand that if significant new findings develop during the course of this study which may relate to my decision to continue participation, I will be informed. I further understand that I may withdraw this consent at any time and discontinue further participation in this study without prejudice to my entitlements to care. Should I choose to withdraw, my condition will continue to be treated in accordance with acceptable standards of medical treatment. I also understand that the investigator of this study may terminate my participation in this study at any time if he/she feels this to be in my best interest.

My signature below indicates my willingness to participate in this research study. A copy of this form has been given to me.

(Subject's Printed Name)

(Subject's SSN)

(Subject's Signature)

() _____
(FMP & Sponsor's SSN)

(Date)

(Principal Investigator's Signature)

520-76-8362
(Principal Investigator's SSN)

(Date)

(Witness's Signature)

(Witness's SSN)

(Date)

Distribution:

- (1) Clinical Investigation Facility (CIF);
- (2) Subject's Medical Record, (to be maintained permanently);
- (3) Principal Investigator;
- (4) Subject.

Subject's Stamp Plate/Identification

Appendix C - Subject Data Collection Sheet

Subject Data Collection Sheet

Blood Sampling Reliability Using Intravenous Lines

Subject Number: _____ Age: _____ Gender: M F

Subject Name: _____

Address and Phone Number: _____

Reason for Emergency Department Visit (Time & Date): _____

Intravenous Line Established Within the Emergency Department? Y N

Size of the Intravenous Catheter: _____ Gauge Location: _____

Type of Fluid Infusing: _____ Amount of Solution Infused: _____

Location of Peripheral Blood Draw: _____

Complications During Sampling? Y N

EXPLAIN if Yes _____

Were there any post-procedural complications reported during the course of the study? _____

Appendix D – Approval Letter from Malcolm Grow Institutional Review Board



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS 89TH AIRLIFT WING (AMC)

24 Mar 00

MEMORANDUM FOR USUHS/CAPT JOHN HIMBERGER

FROM: 89 MDG/SGAT

SUBJECT: Proposed Clinical Investigation Research Protocol – Minimal Risk

1. Your protocol entitled "Blood Sampling Reliability Using Intravenous Lines" was unanimously approved by the MGMC Institutional Review Board (IRB) on March 15, 1999. Your research study has been assigned the number FMG2000-0006H.
2. You may begin your study. Please remember that any subject's personal identification needs to be coded during the data collection in order to protect their privacy and any indirect linkage must be destroyed after data collection is complete.
3. The study requires that an annual/final progress note be submitted to the IRB which should be submitted to the IRB nine months after approval of the study. This will allow time for review and approval of the annual report. The report should be submitted to the IRB (the educational office/TSgt Huff). Failure to submit the report will result in closure of the study. The format for the report must follow the format as described in the Clinical Investigator's Guide.
4. Any abstracts or papers published during the study should also be enclosed; however, they cannot be accepted as an annual or final report as per FDA regulations.
5. If you PCS or retire before the report is due, you must either close the study with a final report or submit a letter signed by the new primary investigator that they will resume responsibilities accompanied by a progress note if the last progress note longer than 3 months ago.
6. Please provide all materials to TSgt Huff, 89 MDG/SGATR; 1050 West Perimeter Rd Andrews AFB, MD 20762-6600. Please call 240-857-6062 or FAX 240-857-4093 or email thule.huff@mgmc.af.mil if you have any questions.
7. We wish you the best in your research efforts. Thank you for your cooperation with the above IRB regulations, and for participation in research at the 89th Medical Center.

//SIGNED//

THULE HUFF, TSGT, USAF
89 MDG Protocol Coordinator

Appendix E – Approval Letter from USUHS Institutional Review Board



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
F. EDWARD HEBERT SCHOOL OF MEDICINE
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799



April 11, 2000

MEMORANDUM FOR CAPT JOHN R. HIMBERGER, GRADUATE SCHOOL OF
NURSING

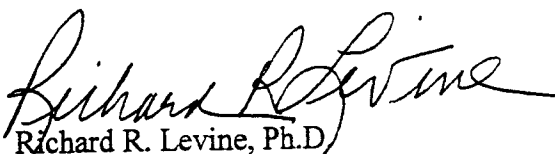
SUBJECT: IRB Approval of Protocol **TO61BF-01** for Human Subject Use

In accordance with USUHS Instruction 3201 and the Memorandum of Understanding for Clinical Affiliation between the Uniformed Services University of the Health Sciences and the U. S. Army Surgeon General designating the Malcolm Grow Medical Center (MGMC) as a clinical affiliate, USUHS accepts the review and approval by the Committee for the Protection of Human Subjects (CHPS) for the research protocol entitled "**Blood Sampling Accuracy using Intravenous Lines**" under your direction. It is requested that MGMC provide this office with human subject use review updates at least annually.

The purpose of this study is to evaluate the accuracy of blood tests obtained from an intravenous line site as compared to the results from samples obtained via venipuncture. This study involves the collection and analysis of blood samples from 30 subjects at Malcolm Grow Medical Center. Each subject will have two blood draws, one using an intravenous line and the other via venipuncture. Each sample will be evaluated for 12 blood test values including WBC; RBC; Hgb; Het; PLT; Na; K; Gluc; CL; CO₂; Cr; and BUN. The IRB understands that all subject identifying information will be coded during the study and destroyed at the completion of the study.

You are required to submit amendments to this protocol, changes to the consent form, adverse event reports, and other pertinent information relative to human subject use for this project to this office for review. It is your responsibility to maintain an accurate and accessible file of all consent forms of participating human subjects.

If you have any questions regarding human subject use, please call me at 301-295-3303.


Richard R. Levine, Ph.D.
LTC, MS, USA
Director, Research Programs and
Executive Secretary, IRB

cc: Director, Research Administration

